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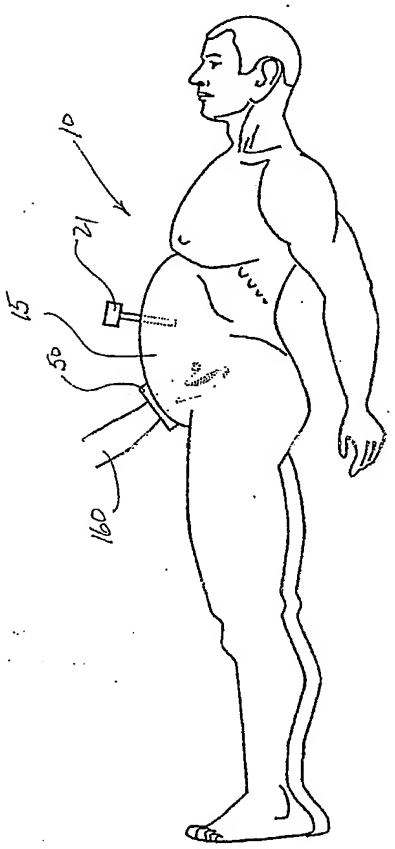

(57) Abstract: A surgical access device facilitates passage of a surgeon's hand through an incision in a body wall and into a body cavity. The device includes a first retention member disposed exteriorly of the body wall, a second retention member disposed interiorly of the body wall, and an elastomeric sleeve. This sleeve has a central section stretchable radially to form an instrument seal around the surgeon's hand, and stretchable axially to form a zero seal in the absence of the surgeon's hand. Stretching of the sleeve is facilitated by varying the size of the first retention member.

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SEALED SURGICAL ACCESS DEVICE

Cross Referenced to Related Applications

This is a non-provisional application claiming the priority of provisional application, serial number 60/449,857 filed on February 25, 2003, entitled Hand Assisted Laparoscopy Apparatus and Method, which is fully incorporated herein by reference.

Background of the Invention

Surgical access to the abdominal cavity of a patient is referred to as "open laparotomy" or "closed laparoscopy." An open procedure involves an incision of sufficient size to allow a surgeon to place hands and instruments through the abdominal wall and into the abdominal cavity. In addition, the open incision must be sufficiently large for the surgeon to clearly see what he or she is doing. Furthermore, open laparotomy often requires multiple retractors, clamps and sponges, all of which compete for limited space around the surgical site.

Laparoscopic or closed surgery eliminates many of the issues surrounding open laparotomy. In a typical pressurized laparoscopy, the abdominal wall is punctured and at least one trocar is inserted into the peritoneum. Gas is introduced into the abdominal cavity and to elevate the abdominal wall away from the internal organs. This results in a large, clear operating field. Additional trocars can be inserted as needed for various procedures. A laparoscope is used to provide visualization of the surgical site.

Instrumentation for laparoscopic procedures has developed prolifically in recent years as the surgeons have become comfortable with "remote-control" approaches to various aspects of surgery. Cutting, dissecting, cauterizing, stapling and suturing have all been addressed by laparoscopic device manufacturers.

Despite the many advantages of laparoscopic surgery, there remain a few complex procedures that make laparoscopy difficult or risky. In some of these cases, a hybrid procedure makes the most sense. If one could have the visibility and open field of an open laparotomy and the control of a closed laparoscopy, one would truly have the best of both procedures. However, the two modalities tend to obviate each other. Indeed, there are some who would argue that many advances in closed laparoscopy would not have occurred had it not been for the availability of an open procedure as a default.

In recent years, a few enterprising surgeons have advanced a method that they call "hand-assisted" laparoscopy or "handoscopy." This involves placing one of the surgeon's hands inside the patient through an enlarged incision, while under laparoscopic visualization.

The challenge now facing the surgeon in this procedure is to provide an adequate sealing means within the enlarged incision. The surgeon's hand must be comfortable, properly placed and free to move with a normal range of motion. In addition, the surgeon should be able to move his/her hand into and out of the abdominal cavity without loss of pneumoperitoneum.

Several devices have been proposed in an attempt to satisfy the requirements of the 'handoscopist." They generally involve an elastomeric seal that fits through an incision and is held in place by retention means on either or both sides of the abdominal wall. The devices are generally complex and require several steps merely to place the device in an operative position. One of the devices requires an adhesive to attach the device to the skin of the exterior abdominal wall. This requires not only application of the adhesive but also a drying time. Allergic reactions and other complications must be considered when using this product. Another device makes use of a "toroidal balloon" that inflates to position the device and seal the incision. The surgeon must overcome the friction and sealing pressure of this device when inserting and withdrawing his/her hand from the surgical site. A further device involves the use of a built-in glove or sheath. This device diminishes the range of motion and the tactile sensation of the hand.

U.S. Patent No. 5,848,992 discloses a surgical access device that allows the conversion of an open procedure to a laparoscopic procedure. In addition, this patent discloses the use of such a device in a case where a large organ is to be removed. In this instance, an incision of adequate size is made initially and sealed with the device at the same time the trocars are being inserted.

Notwithstanding these proposed devices, there remains a continuing need for a surgical access device that provides a flexible, simple and complete seal within an incision of adequate size for the introduction of a human hand.

SUMMARY

The present invention satisfies the requirements of a surgical access device for use in "hand-assisted" laparoscopy or other hybrid surgical procedures that require the use of a human hand within a closed surgical environment.

The present invention in several embodiments makes use of an internal retention member and an external retention member connected by a flexible, lubricious material. At least one of the retention members is tensionable to provide adequate stability to the incision site. A seal is provided that allows the largest range of hand motion without leakage of insufflation gas. The seal is formed of a material that responds well to the presence of glove materials such as Natural Latex, Poly- isoprene, Nitrile, Vinyl or Polyurethane.

In one aspect, the surgical access device of the present invention is adapted to cross a body wall and provide access for a surgeon's hand through an incision in the body wall and into a body cavity of a patient. The device includes a first retention member adapted for operative disposition externally of the body wall, and a second retention member adapted for operative disposition interiorly of the body wall. An elastomeric sheath has an axis that extends from a proximal end through a central section to a distal end. This sheath is stretchable both axially and radially. The proximal end of the sheath is radially stretched to facilitate attachment to the first

retention member while the distal end of the sheath is radially stretched to facilitate attachment to the second retention member. The central section of the sheath is generally radially unstretched to inhibit fluid flow through the sheath when the surgeon's hand is absent from the sheath.

An associated method of use includes the step of inserting the second retention member through the incision leaving the central portion of the tube in the incision. Radially stretching of the central portion of the sheath can be avoided to facilitate formation of a zero seal inhibiting the passage of fluids through the sheath in the absence of the surgeon's hand. These and other features and advantages of the invention will become more apparent with a description of preferred embodiments and reference to the associated drawings.

DESCRIPTION OF DRAWINGS

FIG. 1 is a side view of a patient disposed in a prone position to facilitate a laparoscopic procedure;

FIG. 2 is a top plan view of the patient showing the placement of trocars and an incision of sufficient size to accommodate a "hand-assisted" surgical procedure;

FIG. 3 is a top plan view of the patient showing an access device of the present invention positioned with respect to the incision;

FIG. 4 is a perspective view of one embodiment of the access device of the present invention showing a tubular sheath stretched between two retention members;

FIG. 5 is a perspective view of another embodiment of the access device wherein the sheath includes a plurality of folds;

FIG. 6 is a perspective view of an additional embodiment of the present invention;

FIG 7A-7D are perspective views of another embodiment having a longitudinal seal opening, the views showing progress positions of the retention member between a folded position and an open position;

FIG. 7A is a perspective view illustrating the folded retention member in a closed position;

FIG. 7B is a perspective view of the access device illustrated in FIG. 7a and showing the folded member moving toward an open position;

FIG. 7C is a perspective view showing the folded member further adjusted to the open position;

FIG. 7D shows the folded member in the fully opened position;

FIG. 8A- FIG. 8D are perspective views of a further embodiment having a transverse seal opening, the views showing progressive positions of the retention member between a folded position and an open position;

FIG. 8A is a perspective view illustrating the folded retention member in a closed position;

FIG. 8B is a perspective view of the access device illustrated in FIG. 8A and showing the folded member moving toward an open position;

FIG. 8C is a perspective view showing the folded member further adjusted toward the open position;

FIG. 8D shows the folded member in the fully open position;

FIG. 9 and FIG. 10 are perspective views of an embodiment including adjustment screws, the retention member being shown in an enlarged state in FIG. 9 and in a contracted state in FIG. 10;

FIG. 11 and FIG. 12 are perspective views of an embodiment including a hinge and jack screw for adjusting the size of the first retention member, the seal material being shown in a relatively untension state in FIG. 11 and a relatively tension state in FIG. 12;

FIG. 13 and FIG. 14 are perspective views illustrating an embodiment having two jackscrew adjustments, the seal material being relatively untensioned in FIG. 13 and relatively tensioned in FIG. 14;

FIG. 15 and FIG. 16 are perspective views of an embodiment including detent folding spacers, the seal material being shown in a relatively untensioned state in FIG. 15 and a relatively tensioned state in FIG. 16;

FIG. 17 is a perspective view of a further embodiment wherein the retention member includes a ratchet;

FIG. 18 and FIG. 19 are perspective views of another embodiment wherein the retention member is inflatable, the seal material being shown in a relatively untensioned state in FIG. 18 and a relatively tensioned state in FIG. 19;

FIG. 20 and FIG. 21 are perspective views of an embodiment having two inflatable retention members, the seal material being shown in an untensioned state in FIG. 20 and in a tensioned state in FIG. 21;

FIG. 22 and FIG. 23 are perspective views of an alternate embodiment wherein inflatable retention members are interconnected and disposed in axial planes, the retention numbers being shown in an uninflated cylindrical state in FIG. 22 and in an inflated hourglass state in FIG. 23;

FIG. 24 is a perspective view of a further embodiment wherein the external retention member includes a coil spring;

FIG. 25 is a further embodiment wherein the retention members are formed from two coil springs;

FIG. 26 is a perspective view of an alternative embodiment wherein a body strap is used to maintain the device in a preferred position relative to the patient;

FIG. 27 is a perspective view showing the strap of FIG. 26 in combination with an access device;

FIG. 28 and FIG. 29 are perspective views of an embodiment wherein the seal material is attached to an external retention member by a plurality of adjustable tethers, the material being shown in an untensioned stated in FIG. 28 and in a tensioned state in FIG. 29;

FIG. 30 and FIG. 31 illustrate a further embodiment similar to that of FIG. 28 wherein the interior retention member can be folded as illustrated in FIG. 30 or deployed as illustrated in FIG. 31; and

FIG. 32, 33, 34, and 35 are perspective views illustrating an access device platform including an external retention member the platform being adapted to receive an access device such as the embodiment including tethers as illustrated in FIG. 35;

DESCRIPTION OF PREFERRED EMBODIMENTS AND BEST MODE OF THE INVENTION

A patient 10 is illustrated in Figure 1, and designated by the reference numeral 10. In this view, the patient 10 is shown in a supine position with its abdomen 15 insufflated. A plurality of trocars 20, 21, and 22, best illustrated in Figure 2 are placed so as to provide surgical access across an abdominal wall 15 and into an abdominal cavity 16. Various surgical instruments are adapted for use through the trocars 20, 21, and 22.

In Fig. 2 and FIG. 3 a "hand-assisted" laparoscopic procedure is shown. The patient 10 is supine and the abdomen 15 is insufflated. In addition to the trocars 20, 21, and 22, there is an additional surgical access device 50 that has been placed over a surgical incision 100. The surgeon has placed his or her hand 160 (Figure 1) through the access device 50 and into the abdominal cavity 16 of the patient 10. With this accommodation, the surgeon is able to use the inserted hand 160 to perform tasks that are too difficult or not safe with the instruments normally used in laparoscopy.

The access device 50 provides a gas tight seal so that the insufflated, pressurized abdomen 15 does not collapse. The access device 50 may also

accommodate large, contaminated specimens or diseased organs or tissue which need to be removed from the abdominal cavity 16. Instrumentation or tools that might otherwise be too large for a trocar may be introduced through the access device 50 and subsequently attached to device drivers operated through the trocars 20, 21, and 22. In addition, specimen bags that may be introduced through one of the trocars 20-22 can be removed fully burdened through the access device 50.

As illustrated in Figs 3 and 4, the access device 50 can be placed through a surgical incision 100; and retained against the external abdominal wall 16 by a first enlarged retainer 55, and against the internal abdominal wall 18 by a second enlarged retainer 65. The external first retainer 55 supports a gas tight membrane or sheath 75 at a first end 76. The internal second retainer 65 supports the gas tight sheath 75 at a second, opposite end 86. The two opposing ends 76 and 86 maintain a communicating surface 77 that passes through the incision 100. The material forming the sheath 75 of the surgical access device 50, provides a durable and non-permeable surface against the incised tissue of the incision 100.

With particular reference to FIGS. 4, 5, 6, a preferred embodiment of the surgical access device 50 is shown to include a first end 51, a second end 52 and a communicating middle portion 53. At the first end 51, the first retainer 55 comprises an enlarged and adjustable hoop 56. The exact shape of the hoop 56 may be circular, ovoid, rectangular, square, triangular or the like. The first end portion 55 is sized and configured to be adjustable in size or area so that the surface 77 of the sheath 75 is appropriately stretched or tensioned. A preferred embodiment of the access device 50

includes the hoop 56 in the form of an overlapping leaf spring that is biased to the open condition. As opposing ends 57, 58 of the leaf spring spread apart, appropriate tension is exerted upon the sheath 75. The applied tension causes a pulling force to be exerted through the communicating middle portion 53 which tend to draw the second, internal or distal end 52 of the access device 50 into proximity with the inner surface of the abdominal wall 18.

The second retainer 65 is preferably constructed of a flexible material that allows it to be inserted into the surgical incision 100 in a folded form having a reduced profile. The second retainer 65 is preferably self-deploying or, at least, has sufficient memory to return to a preferred, somewhat circular, or enlarged shape without manipulation. The material choices for such a configuration may include flexible vinyl, rubber, silicone or other elastomeric. The materials may also include rigid materials, like rigid plastic or metal, that are hinged or provided with flexible portions.

In addition, the construction of either the retainers 55, 65 may include the use of elastomeric components that have been fitted with or have been molded to include shape memory metals, such as Nickel-Titanium (NiTinol). In any case, the second retainer 65 is easily deformable to a condition or shape that facilitates introduction into the smallest possible surgical incision 100.

It must be kept in mind that the second retainer 65 must be sized and configured to retain the access device 50 in place during the rigors of an active surgical procedure, and do so without causing tissue damage such as tissue necrosis or abrasion. A preferred embodiment of the second retainer 65 comprises a ring 66 of soft silicone or

vinyl with an internal, encapsulated or insert molded Nickel-Titanium support ring. This embodiment may be introduced in a very deformed condition and will subsequently recover to the preferred shape and size upon completion of introduction into the body cavity 16.

As an alternative, the super-elastic and shape-memory properties of Nickel-Titanium may be drawn from temperature transition properties of the alloy. For instance, the second retainer 65 may be cooled to a temperature at which the ring 66 is easily deformable to a high degree; then, as the alloy warms to body temperature, the retention member 65 automatically returns to its programmed form, size or configuration.

The sheath or membrane 75 is shaped by the tension between the first retainer 55 and the second retainer 65. It may initially define an orifice 78, such as a slit or hole, that communicates between the exterior and the interior of the body cavity 16. The orifice 78 exhibits a first condition when the sheath 75 is not under tension and at least one second condition when the sheath is under tension.

In a preferred embodiment, the tensioning of the sheath 75 adjusts the orifice 78 to a preferred size and configuration. In a preferred embodiment, this configuration includes a radiused, funnel-shaped orifice 78 at the first end 51; transitions to a smaller diameter at the middle portion 53; and again transitions to a funnel-shaped enlargement 67 at the second end 52.

The material of a preferred embodiment of the sheath 75 may include a non-distensible or non-elastic material such as polyethylene, polyurethane or reinforced

elastomeric. The choice of polyethylene film as a sheath 75 provides a nearly friction-free surface 77 against most glove materials. Since the polyethylene material is non-elastic, the sheath 75 can be folded into discrete "fan-fold" segments 79. Such a condition will allow the sheath 75 material to be compressed radially by the adjacent body tissue so that it forms a throat 90 or nearly occluded middle portion 53, when no hand or instrument is present within the orifice 78 of the device 50. When a hand or instrument is present, the fan-folded segments 79 at the throat 90 of the sheath 75 yield to the size and shape of the inserted hand 160 (Figure 1) or instrument, but importantly also form an occlusive seal. Bearing in mind that the normal pneumoperitoneum is only about 0.18 to 0.28 psi, this seal along the throat 90 is adequate.

With reference to Figures 7A-7D, and Figures 8A-8D, another embodiment of the surgical access device 50 of the present invention comprises a circular first retainer 155 that is diametrically folded. In Figures 7A-7D, the orifice 78 is elongate along the fold, while in Figures 8A-8D the orifice 78 is elongate transverse to the fold. In either case the folded sheath 75 allows the second retainer 65 to be easily inserted into a surgical incision 100. The subsequent unfolding of the first retainer 155 by forcing apart the folding halves 156, 157 as shown in Figures 7B and 7C, results in a stretching of the sheath 75. In Figure 7D, the two halves 156, 157 of the first retention member 155 are shown in a locked, flattened condition with the sheath 75 in tension.

In Figures 7A-D the embodiment of the folded first retention member 155 comprises an orifice 78 that is elongate and in line with the fold 159 of the sheath 75, and the hinged portions 158 of the first retention member 155. In the alternative

embodiment of the Figures 8A-8D, the folded first retention member 155 comprises an orifice 78 that is elongate but transverse to the fold 159 of the sheath 75, and the hinged portions 158 of the first retention member 155.

With reference to Figures 9-17, a surgical access device 50 is shown having a first retention member 55 that is adjustable in area or circumference. Two halves 156, 157 of the first retention member 155 may be separated along a common plane by adjusting members including adjusting nuts 200, 220 and adjusting screws 210, 230, respectively. This action will place the sheath 75 under tension so as to prepare the orifice 78 for use. There may be a plurality of these adjusting members, say two, three, four or more, that cooperate to stretch the sheath 75 appropriately, as illustrated in Figure 10.

Specifically referring to FIGS. 11, 12, a surgical access device 50 according to the present invention is shown having at least one hinge 260 that permits the first retainer halves or segments 156, 157 to move in opposing directions upon application of a spreading force. Such a spreading force may be applied by rotation of a jack-screw and thumb-wheel combination 265. The spreading force causes the orifice 78 to assume a predetermined shape, for example as illustrated in Figure 12.

With reference to FIGS. 13, 14, there is shown a surgical access device 50 according to the present invention wherein the elongate orifice 78 is positioned so as to be stretched along its transverse midline 278. This configuration causes the orifice 78 to assume a more closed natural condition than would be the case wherein the elongate orifice 78 is transverse to the stretching moment. A combination of in-line and

transverse stretching of the sheath/membrane 75 and the orifice 78 results in a more symmetrical opening of the orifice 78 as shown in FIG. 14.

Referring now to FIGS. 15 and 16, the surgical access device 50 is shown with the two separable members 156 and 157. The separable member 156 in this embodiment forms a semicircle extending between ends 161 and 162. Similarly, the separable member 157 extends between ends 163 and 164. In this embodiment, the ends 162 and 164 have an abutting relationship and are joined by a foldable separation member 280. Similarly, the ends 161 and 163 have an abutting relationship and are joined by a foldable separation member 290. The separation members 280 and 290 are held in a naturally folded state as illustrated in FIG. 15 by the tension of the sheath 75. However, when the separable members 156 and 157 are drawn away from each other, the separation members 280 and 290 elongate through an over-centered condition to hold the separable members 156 and 157 in a separated state as illustrated in FIG. 16.

The elongate orifice 78 may be orientated either in-line or transverse to the direction of stretch. In an additional embodiment of the surgical access device 50 may comprise the foldable, extendable separation members 280, 290 wherein the stretching of the sheath 75 is more or less omni-directional. The foldable separation members 280, 290 may be constructed of metal with or without a discrete hinges, or may be constructed plastic with either discrete or "living" hinges.

In yet another embodiment illustrated in Fig. 17 a surgical access device 50 according to the present invention has the generally circular first retention member 155 and the malleable or foldable second retention member 65. The first retention member

155 comprises a length of rigid material formed into a hoop or coil 151 having opposing ends 277, 280 which are spreadable relative to each other to enlarge a hoop or coil 151. When the coil 151 is enlarged, the tension upon the attached sheath 75 is increased.

The position of the ends 277, 280 can be maintained by a first ratchet member 275 that engages a second ratchet member 276 in a unidirectional relationship. The ratchet configuration may be formed at only one of the ends 277 and 280, or alternatively, at both of the ends 277 and 280. In the latter regard, the double-ended ratchet configuration results in a very large distention potential for the first retention member 155 and accordingly for the sheath 75.

The ratchet configuration of the surgical access device 50 is preferably constructed of a rigid plastic material such as polycarbonate, ABS, PVC or other filled or non-filled material. In a similar embodiment the first retention member 155 is made from metal and therefore sterilizable and reusable by fitting it with a new, disposable sheath 75 and second retention member 65.

With reference now to FIGS. 18, 19, 20, 21, a surgical access device 50 according to the present invention is shown with an inflatable or fillable first retention member 300, and a malleable foldable or otherwise deformable second retention member 65. In a preferred embodiment, the first inflatable or fillable retention member 300 comprises a torroidal hollow structure 310. The hollow structure 310, when uninflated or un-filled, exerts very little, if any stretching or tensioning force upon the sheath/membrane 75. However, when the hollow structure 310 is inflated or filled, as

shown in Figure 19, it assumes a larger diameter and area with a concomitant stretching or tensioning of the sheath 75.

Since a preferred embodiment of the invention comprises a non-distensible or non-elastic sheath 75, it follows that the stretching of the sheath 75 is accompanied by a tensioning of the middle section 53. This tensioning of the middle section 53, that connects the first retention member 300 and the second retention member 65, tends to draw the second retention member 65 into sealing engagement with the interior side of the abdominal wall 15, resulting in a formation gas tight seal around the access device 50.

With attention drawn specifically to FIGS. 20, 21, there is shown a surgical access device 50 according to the present invention wherein the first retention member 300 is an inflatable or fillable structure 310, and a second retention member 365 is also an inflatable or fillable structure 375. The second retention member 365, when un-inflated or unfilled may be easily inserted through the incision 100 into the body cavity 16 (Figure 1), and subsequently inflated or filled to assume a more or less rigid or definite shape within said body cavity 16. The first retention member 300 may then be inflated or filled to provide the external retention and the concomitant stretching or tensioning of the sheath 75. In a preferred embodiment, the sheath 75 that connects the two inflatable or fillable retention members 300, 365 can be formed as a single layer or thickness of non-distensible or non-elastic material and will typically be uninflated. The integrity of the retention members 300, 365 is largely dependant upon the sheath 75 which is preferably provided with a minimum of intrusive material along the middle

section 53 which passes through the incision 100. This material 75 along the middle section 53 or the throat of the access device 50 is preferably smooth, lubricious, thin and appropriately constructed so as to be non-bulky.

An additional embodiment of the access device 50 of the present invention is shown in FIGS. 22, 23 wherein an open-ended, generally cylindrical sheath 455 is constructed with a plurality of axially aligned, communicating, hollow, inflatable, fillable members 380 extending between a proximal end 463 and a distal end 465. The communicating members 380 can be inflatable or fillable by means of a communicating tube 410 connectable to an inflating or filling means (not shown). The generally cylindrical shape of the access device 50 can be easily compacted to facilitate placement of the distal end 465 through the surgical incision 100 and into the body cavity 16. As the access device 50 is inflated or filled, however, it assumes an "hour-glass" shape as shown in Figure 23; with a first retention portion 400, a second retention portion 460, and a middle section 53 therebetween.

This embodiment is of particular advantage since, the longitudinal or axial seams or abutments 381 of the individual inflatable or fillable members 380 prevent material motion and also minimize surface contact between a gloved hand of the surgeon and the material of the middle section 53. The lumen of the middle section 53 may be lubricated with a thick or viscous material that is maintained within the interstices 382 of the abutting or adjoining inflatable or fillable members 380. The lubricant may facilitate formation of an instrument seal between the inserted gloved hand and the lumen, in addition to perfecting the self-sealing function of the access device when no inserted

hand or instrument is present. The use of a non-distensible or non-elastic material is again recommended for use, so that friction is minimized and the material from which the middle section 53 is made does not gather or fold as a gloved hand or large instrument is repeatedly inserted and withdrawn.

With reference to Fig. 24, a surgical access device 50 according to the present invention is shown wherein a compressible helical coil member or spring 550 forms a first retaining member 500. The coil member 550 may be deformed so as to minimize the tension upon the attached sheath 75 and the traversing portion 53. The second retaining member 65 may be deformed and placed within the surgical incision 100 (Figure 2) so that upon release or decompression of the coil 550, the second retaining member 65 is appropriately approximated to the interior of the abdominal wall 15. The coil 550 of the first retaining member 500, in a preferred embodiment, may be contained within a containment pouch, bag, box or the like for delivery in a compact configuration thereby exerting a minimum tension upon the attached sheath 75.

Referring now to Fig. 25, there is shown an alternate embodiment of the access device 50 of the present invention wherein the first retaining members 500, is accompanied by a second retaining member 565 having a helical coil member or spring 570. The second retaining coil member 565 may be introduced through an incision 100 in a compact configuration and subsequently released to assume an enlarged diameter and an enlarged area of contact with the interior surface of the abdominal wall 15. The subsequent release of the compact coil 550 of the first retaining member 500 results in a stretching or tensioning of the attached sheath 75.

With reference to FIGS. 26, 27, there is shown a surgical access device 50 that is adapted to be held in position over a surgical incision 100 by a strap or belt assembly 600. For clarity, the belt assembly 600 is illustrated absent the access device 50 in Figure 26, and in combination with the access device 50 in Figure 27. The belt assembly 600 may include, for example, two belts 605 and 610 each having an associated attachment means or buckle 620 and 640, respectively. The two belts 605 and 610 can be joined by a platform member 645 provided with an aperture 647 of sufficient size to receive an access device 650. The belt 605 and 610 are of suitable length to extend around the torso of the patient 10 (Figure 1), with the platform 645 positioned over the incision 100. In this manner, the belt assembly 600 can be used to stabilize the access device 650 relative to the incision 100.

With reference to FIGS. 28, 29, a surgical access device 50 is shown with the solid, rigid ring or retainer 155, in this case the retainer 155 is provided with a plurality of slits 282 sized and configured to engage and releasably hold an associated tether 283 in each slit 282. Each of the tethers 283 is connected at a first end 285 to the sheath 75, and at second opposite end 286 to an enlarged feature 284 which retains the associated tether 283 within the slits 282. The enlarged feature 284, in a first instance, acts as a stop to prevent the associated tether 283 from being drawn completely back through the associated slit 282. The enlarged features 284, in a second instance, acts as a handle with which the tethers 283 can be grasped and tensioned.

In a preferred embodiment the slit 282 in the solid ring 155, are tapered toward the bottom of the slit 282 so as to compress the traversing tether 283 and thereby

increase the frictional engagement. The tether 283 may be adjusted or released from the ring 155 by lifting the tether 283 from the narrowest, bottom portion of the slit 282. The sheath 75 is tensioned within a surgical incision 100 as the tethers 283 are drawn outwardly through the slits 282. As with previous embodiments, this tensioning tends to draw the second retaining portion 65 toward the interior surface of the abdominal wall 15.

The embodiment illustrated in Figures 30 an 31 is similar to that shown in Figures 28 and 29, at least with respect to the construction associated with the tethers 283 and ring 155. However, in the embodiment of Figure 30, the second retention member 65 is illustrated to have a foldable construction. When folded, the second retention member 65 has a smaller profile facilitating insertion through the incision 100 (Figure 2), as shown in Figure 30. When the second retention member 65 is unfolded as illustrated in Figure 31, it assumes an enlarged profile facilitating its anchoring and sealing function with respect to the abdominal wall 15 (Figure 1).

With reference to Figures 32, it can be seen that a stabilizing platform 600 can be adapted for use in hand-assisted laparoscopy. The platform 600 may include a base 601, at least one support member 603 and a transverse cross-member 605. The base 601 is sized and configured for placement beneath the surgical patient 10 (Figure 1). The support members 603 extend upwardly from the base 601, while the cross-member 605 is connected to support the access device 50, such as that shown in Figure 5, across the patients abdomen, chest or pelvis.

A hand-assisted laparoscopic procedure requires that a human hand be inserted and withdrawn several times while maintaining pneumoperitoneum. The access channel or entry port, through which the hand is inserted and withdrawn, must fit tightly around the wrist of the surgeon. When the hand is removed, the access device forms an air-tight or zero seal. With this construction, the inflated abdominal wall experiences changes in pressure and elevation as the hand is inserted and removed. It is under these circumstances that the support system 600 can be of particular advantage in providing a stable platform for the access device 50.

A preferred embodiment of the support system 600 provides an adjustable mounting ring 607 to which the access device 50 can be attached. The mounting ring 607 may pivot to accommodate the appropriate position of the surgical incision 100. The pivotal adjustments of the support members 603 and the cross-member 605, also facilitate use of the system with patients of various sizes and weights.

In several embodiments of the support system 600, the base 601 may be fastened to the surgical table with the support members 603 extending upwardly from one or both sides of the patient 10 for connection to the cross-member 605.

The foregoing disclosure relates generally to hand assisted laparoscopy, and discloses many different aspects of structure as well as methods of manufacture and use. While the disclosure has been facilitated by describing each aspect in a particular embodiment or context, it will be apparent that a particular aspect may be equally applicable to other embodiments including those described in this disclosure. By way of example, and not limitation, it will be noted that the aspect of a hinged inner ring,

illustrated in the two-ring embodiment of Figure 30 may also be advantageously applied to the embodiment illustrated in Figure 10. Accordingly, the full scope of the invention should not be limited by the disclosed embodiments, but rather should be determined only with reference to the following claims.

CLAIMS

1. A surgical access device adapted to extend across a body wall and provide access for a surgeon's hand through an incision in the body wall and into a body cavity of a patient, the access device comprising:

a first retention member adapted for operative disposition exteriorly of the body wall;

a second retention member adapted for operative disposition interiorly of the body wall;

an elastomeric sleeve having an axis extending from a proximal end through a central section to a distal end, the sleeve being stretchable axially and radially;

the proximal end of the sleeve being radially stretchable to facilitate attachment to the first retention member;

the distal end of the sleeve being radially stretchable to facilitate attachment to the second retention member; and

the central section of the sleeve being generally unstretched radially to form a zero seal and thereby inhibit fluid flow through the sleeve when the surgeon's hand is absent from the sleeve.

2. The surgical access device recited in Claim 1, wherein first retention member forms a hoop.

3. The surgical access device recited in Claim 2, wherein the hoop is circumferentially adjustable.

4. The surgical access device recited in 2, wherein the hoop has the shape of a circle and is foldable along a chord of the circle.

5. The surgical access device recited in Claim 1, wherein the proximal end of the sleeve includes a plurality of fan folds.

6. The surgical access device recited in Claim 3, wherein the hoop is formed as a coil.

7. The surgical access device recited in Claim 2, wherein the hoop is inflatable.

8. The surgical access device recited in Claim 6, wherein the coil includes a ratchet.

9. The surgical access device recited in Claim 3, wherein the hoop includes at least one threaded member operable to adjust the size of the hoop.

10. Method for accessing a body cavity through on incision in a body wall with a surgeon's hand, the method comprising the steps of:

providing an access device with a first retention member, a second retention member, and an elastomeric tube having a proximal end and a distal end;

radially stretching the proximal end of the tube for attachment to the first retention member and radially stretching the distal end of the tube for attachment to the second retention member.

inserting the second retention member through the incision leaving the central portion of the tube to extend through the incision; and

avoiding any radial stretching of the central portion of the sleeve to form a zero seal inhibiting the passage of fluids through the sleeve in the absence of the surgeon's hand extending through the sleeve.

11. The method for accessing a body cavity recited in Claim 10, wherein:

the providing step includes the steps of providing the first retention member in the form of a hoop.

12. The method for accessing a body cavity recited in Claim 11, further comprising the step of:

circumferentially adjusting the hoop to change the size of the hoop.

13. The method for accessing a body cavity recited in Claim 11, wherein the hoop has the general shape of a circle and the method further comprises the step of;

folding the hoop along a chord of the circle.

14. A method for accessing a body cavity recited in Claim 12, wherein adjusting step includes the step of inflating the hoop to change the size of the hoop.

15. A method for accessing a body cavity recited in Claim 12, wherein the adjusting step includes the step of:

ratcheting the hoop to change the size of the hoop.

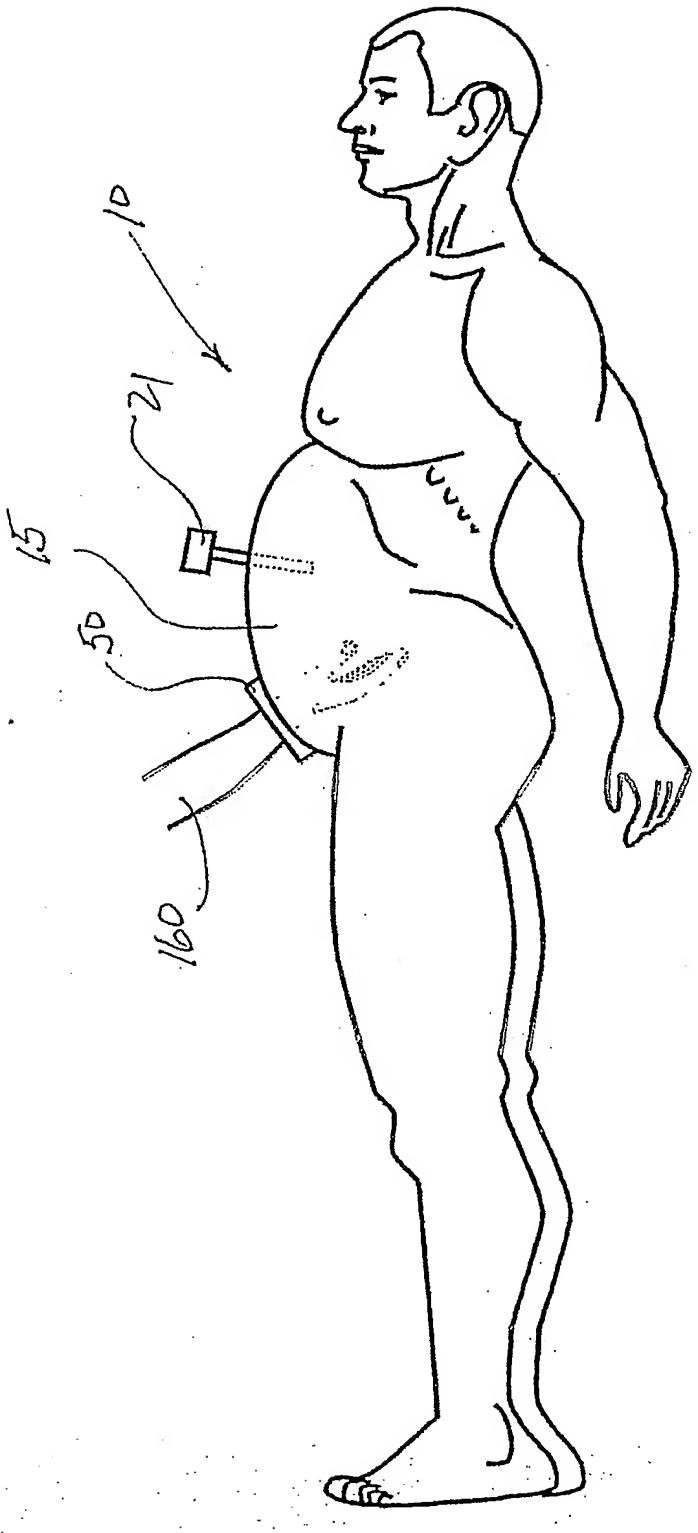


Fig. 1

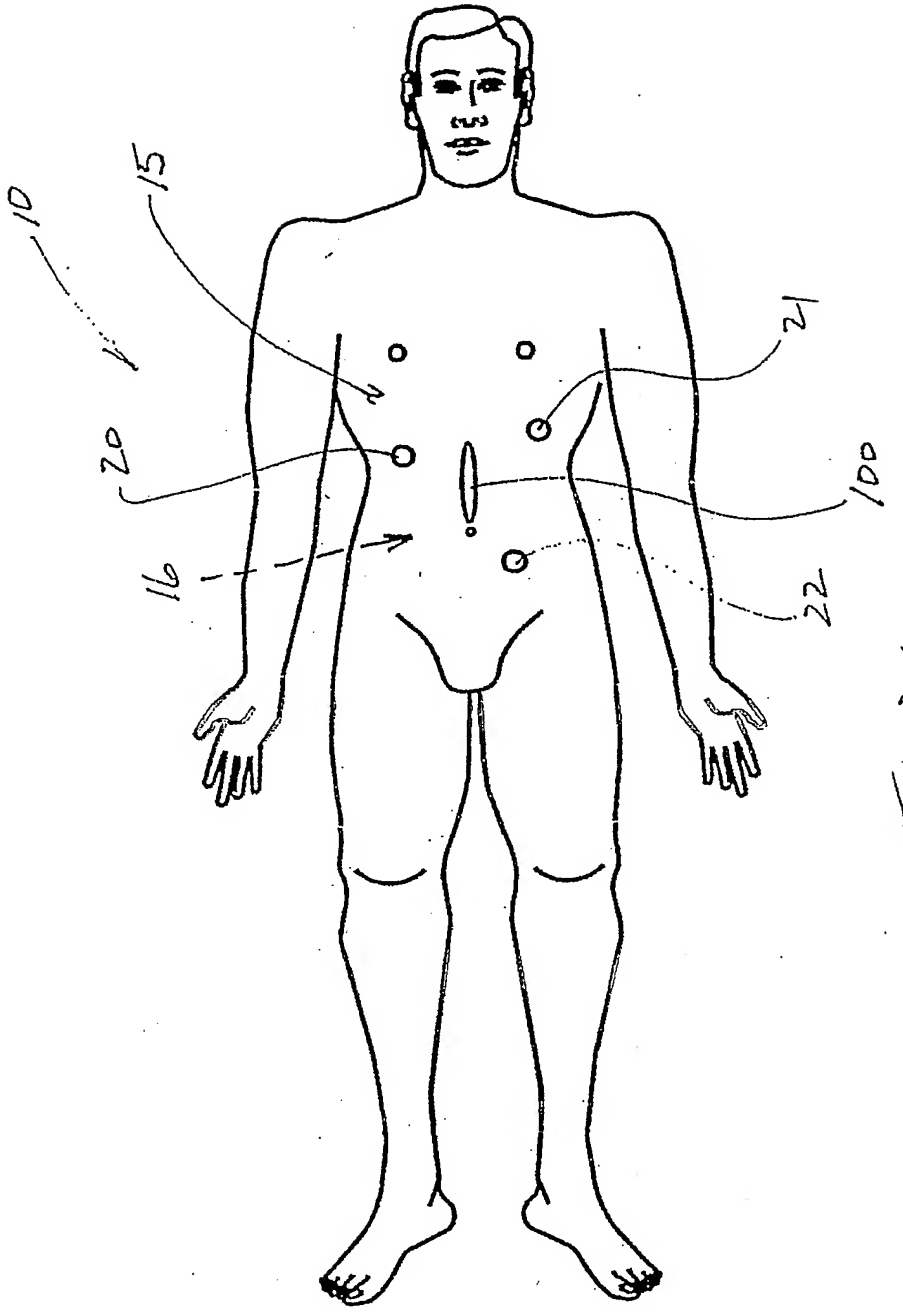
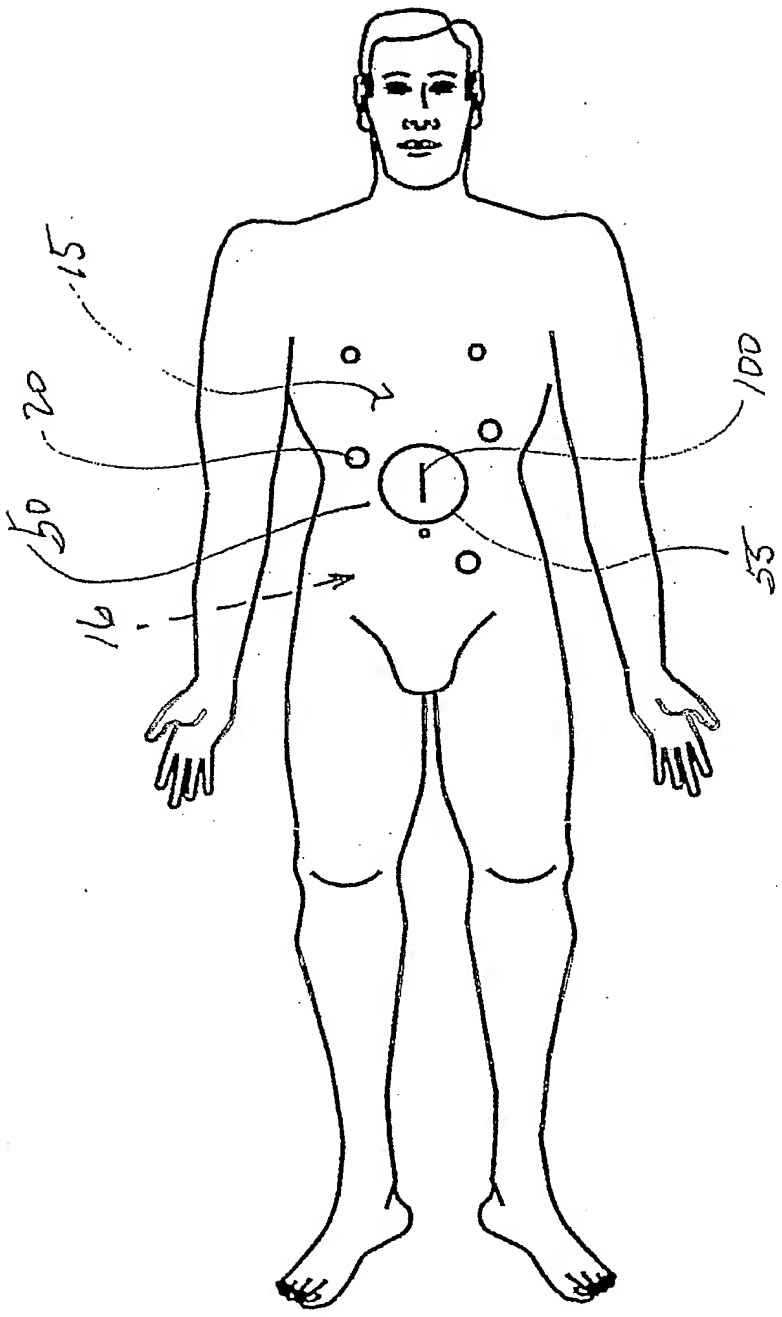


Fig. 2



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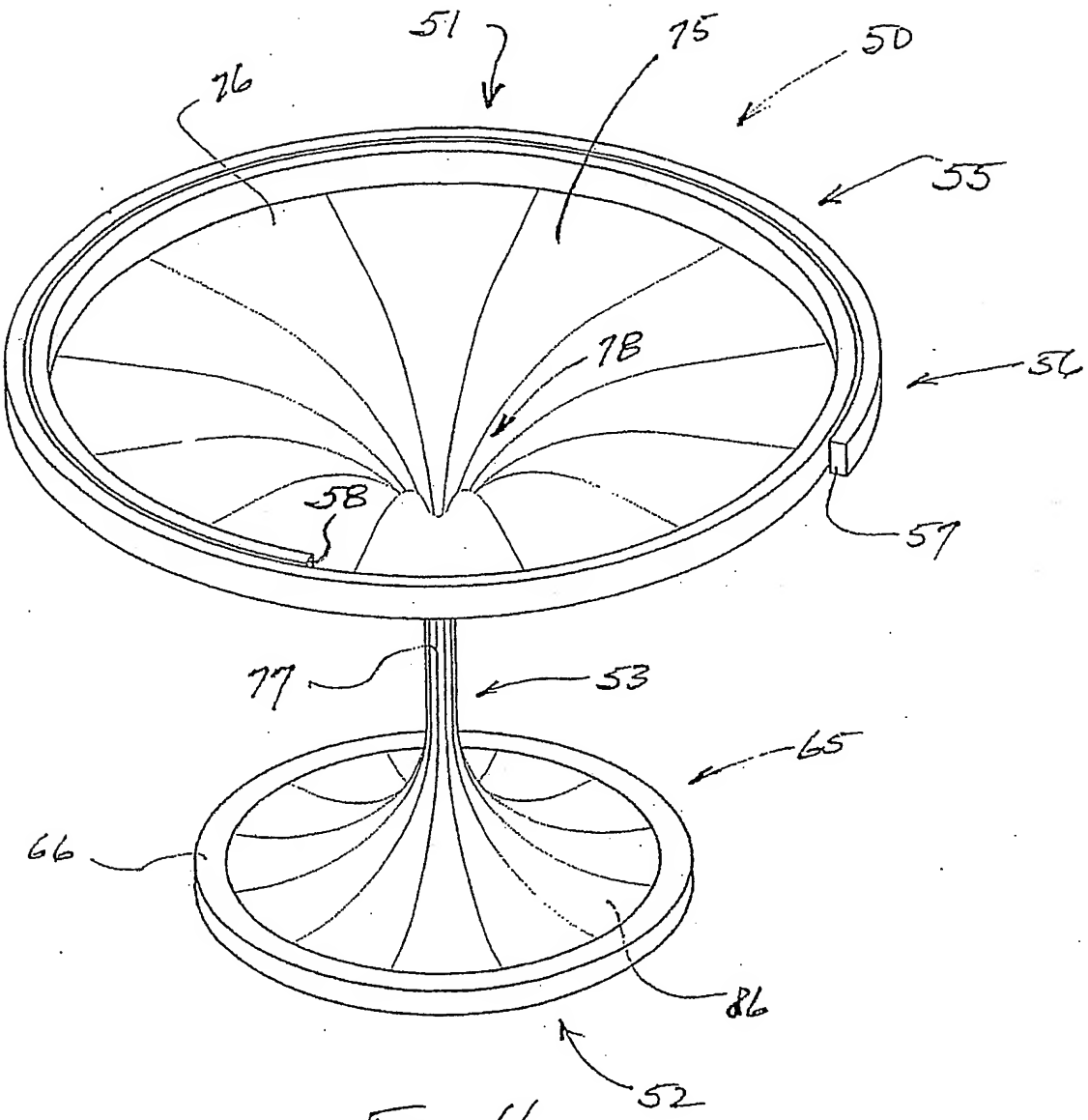

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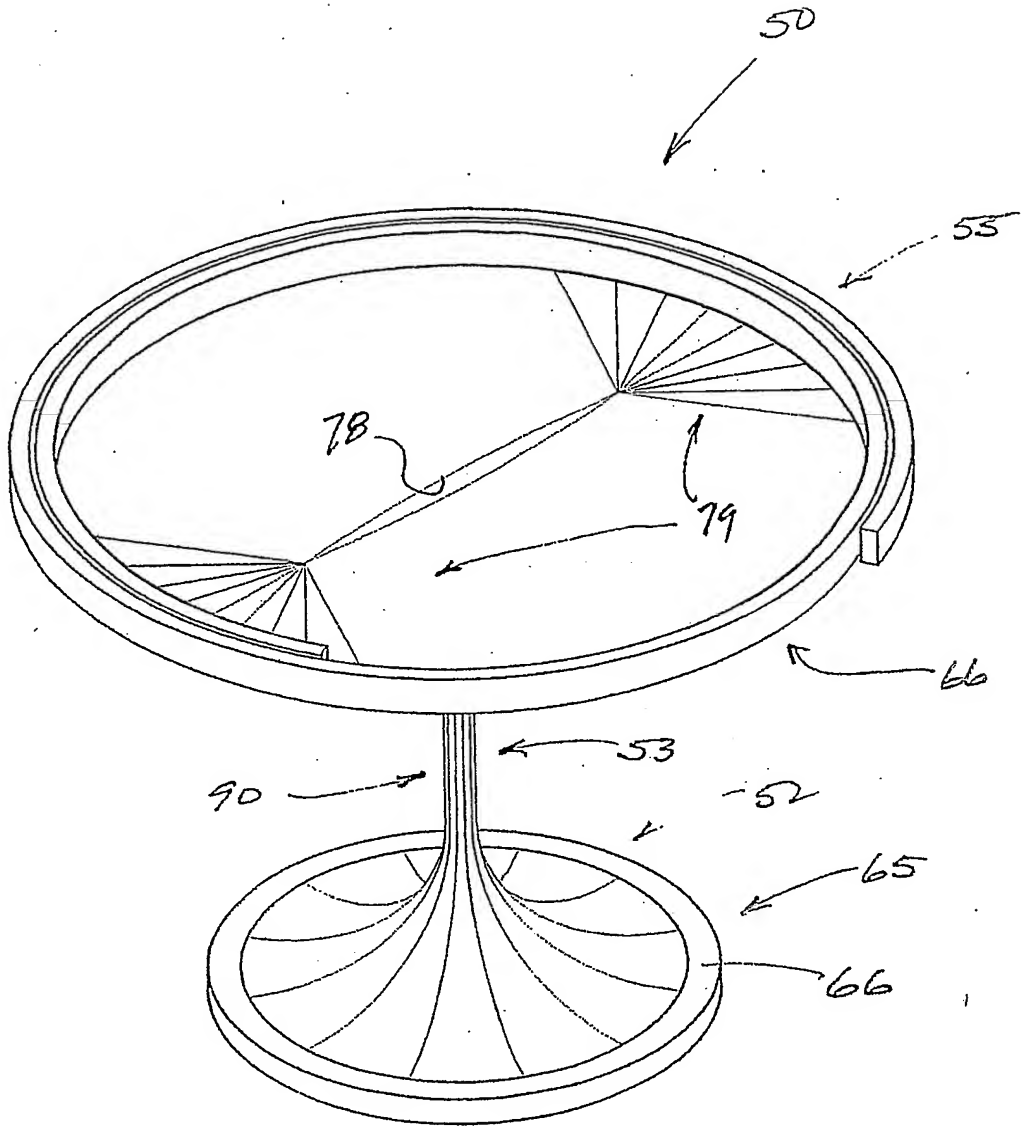


Fig. 5

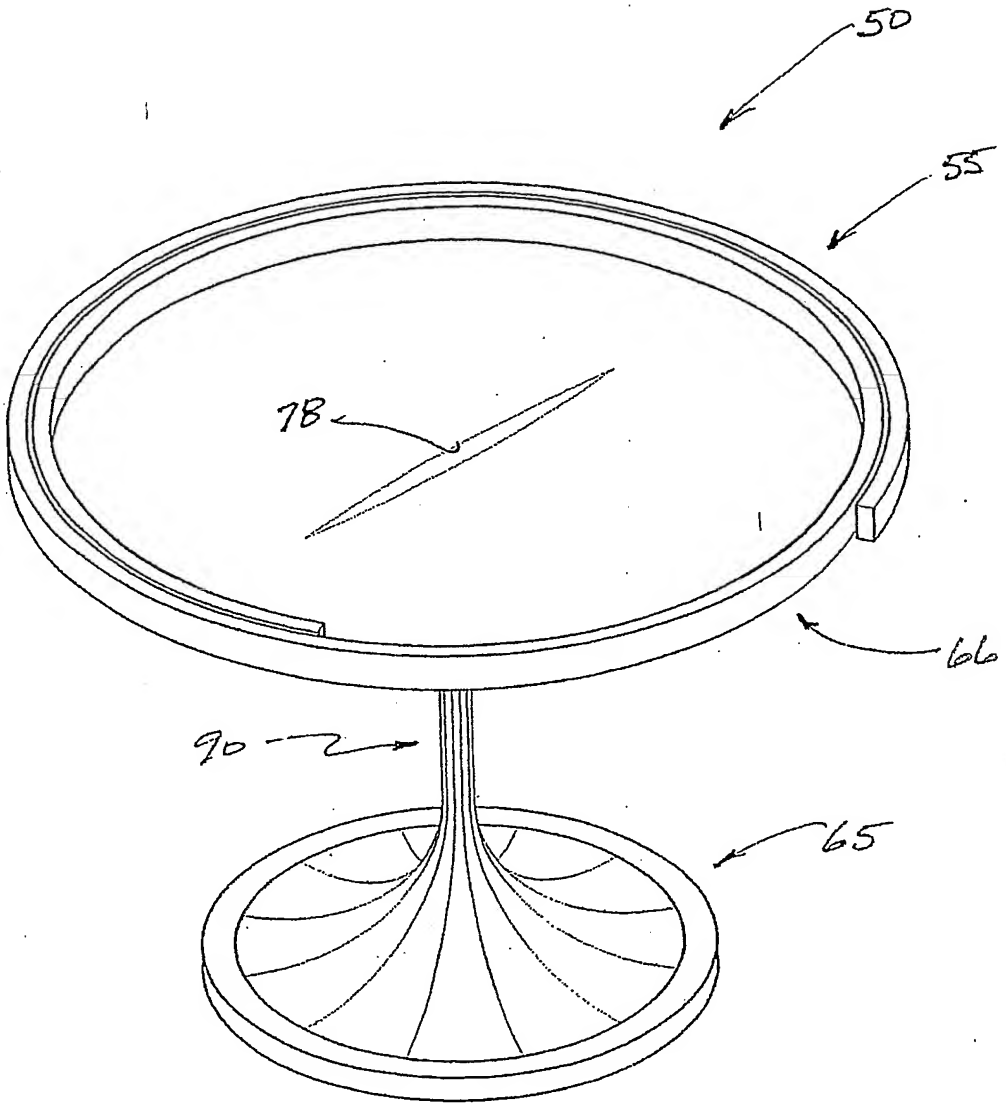


Fig. 6

Fig. 7A

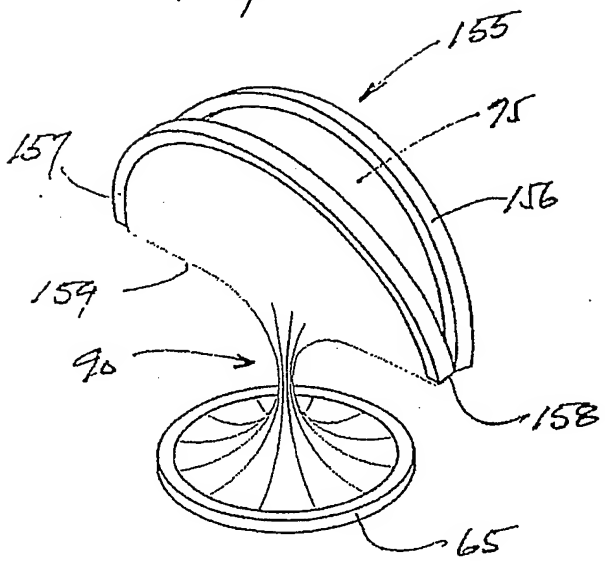
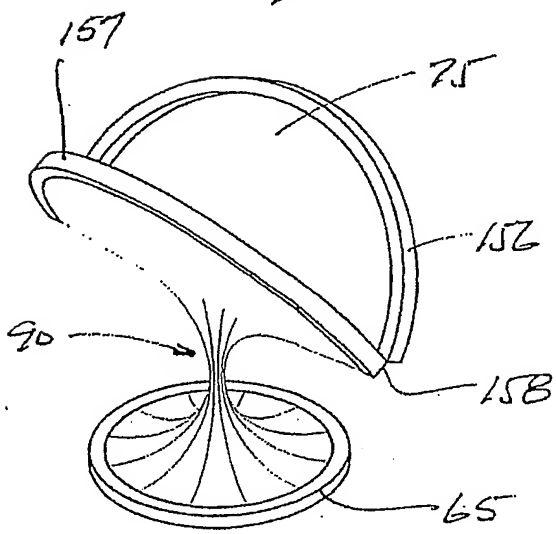


Fig. 7B



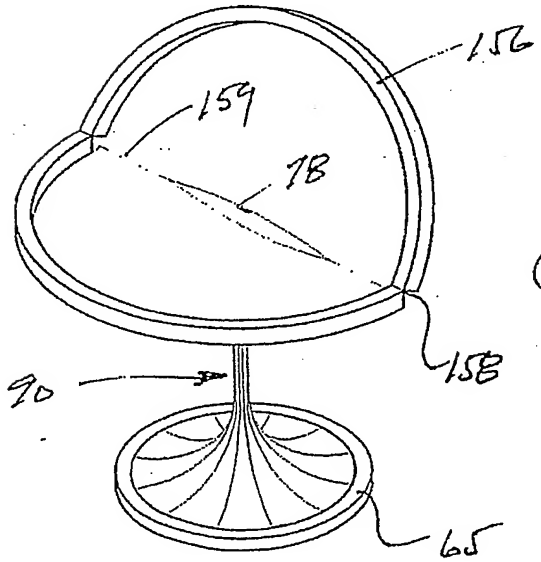


Fig. 7C

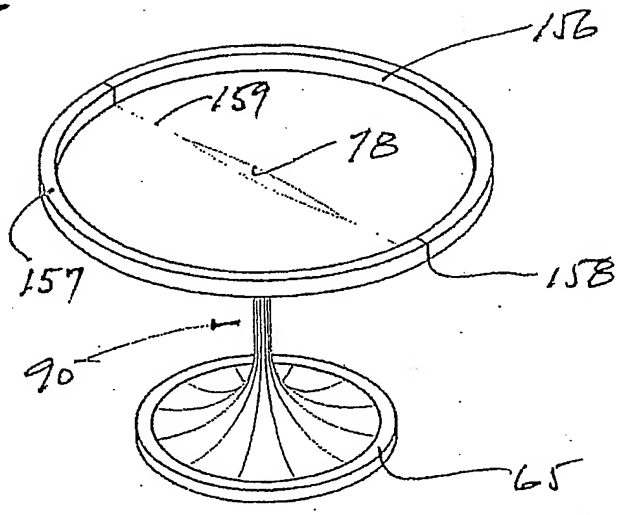


Fig. 7D

Fig. 8A

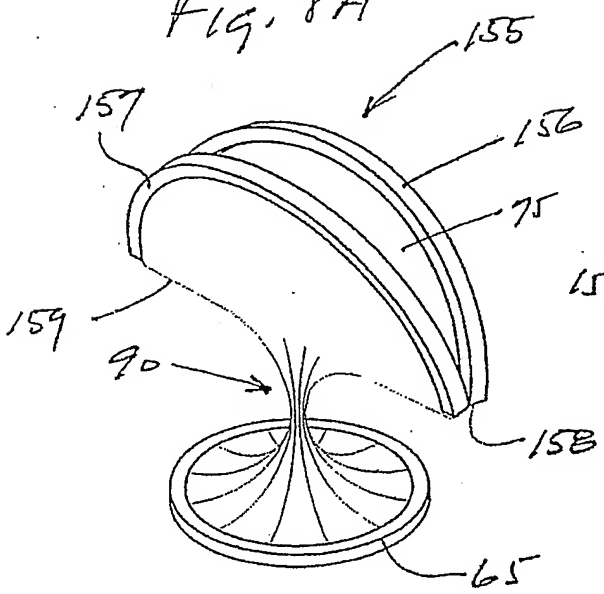
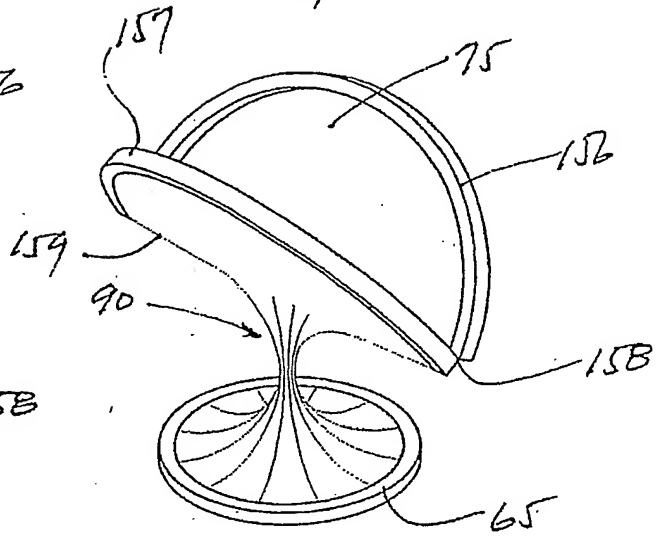


Fig. 8B



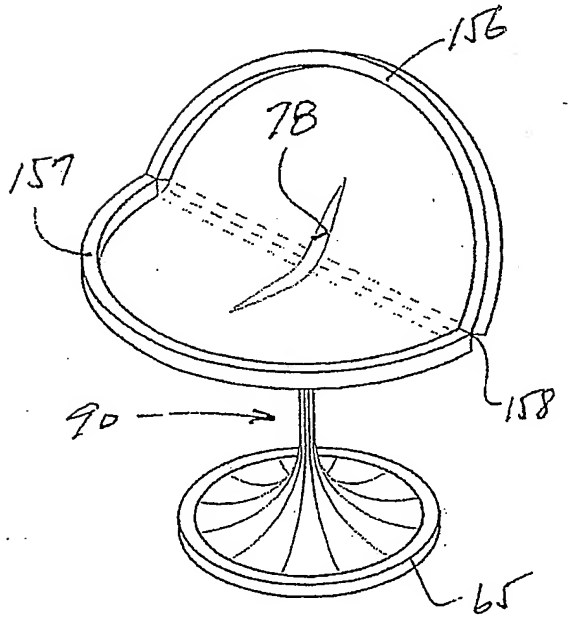


Fig. 8C

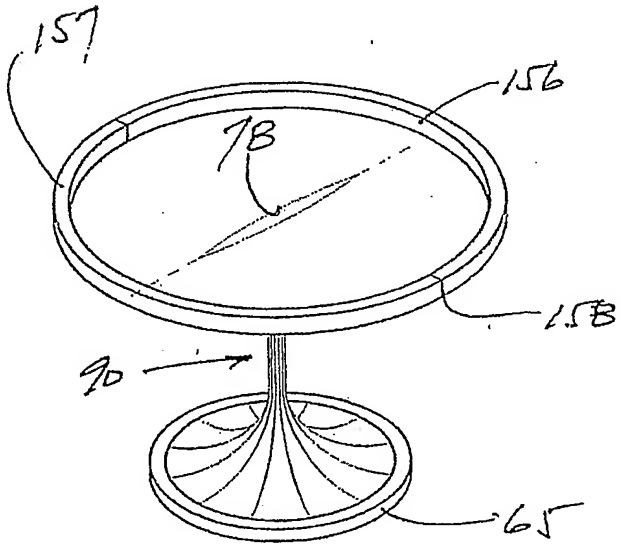
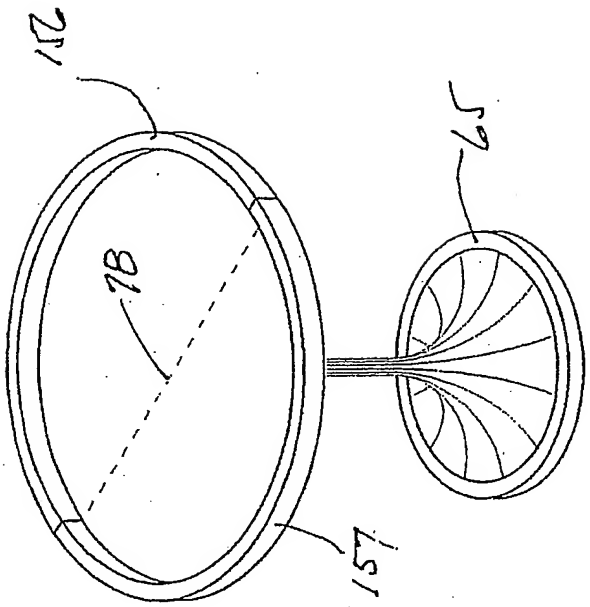


Fig. 8D



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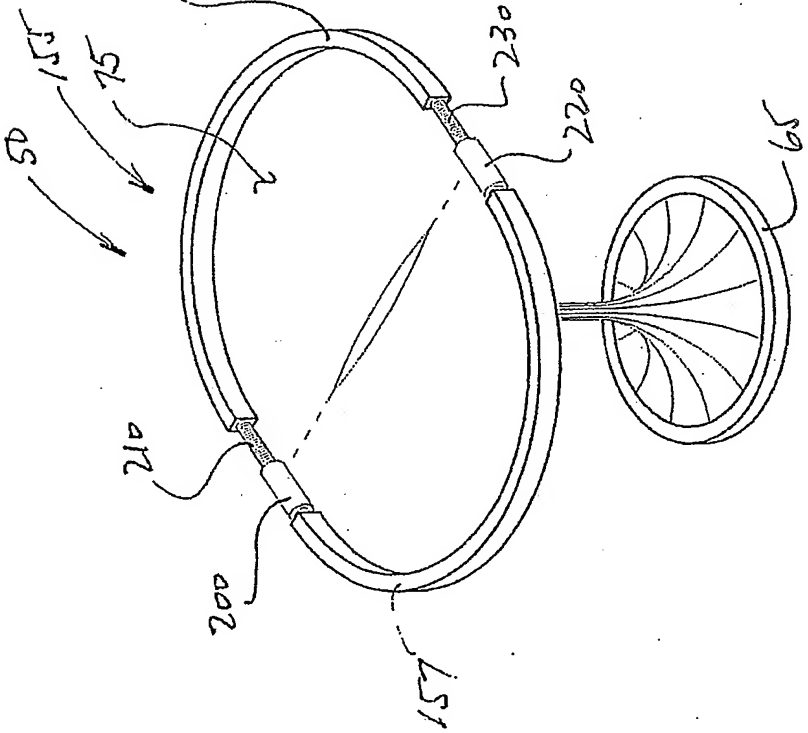

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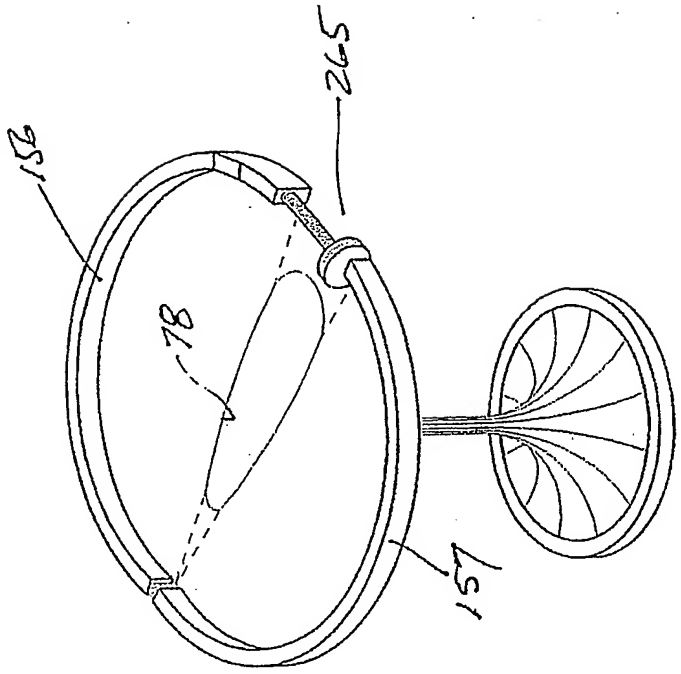
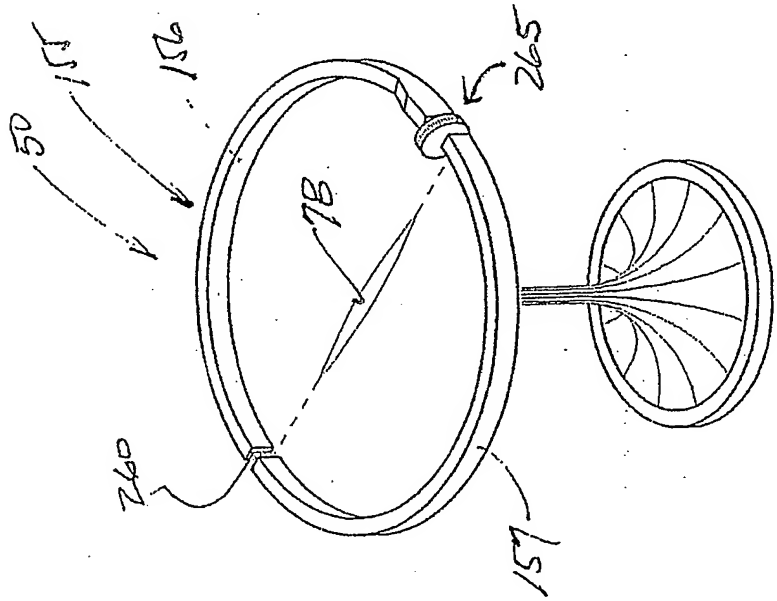


Fig. 12



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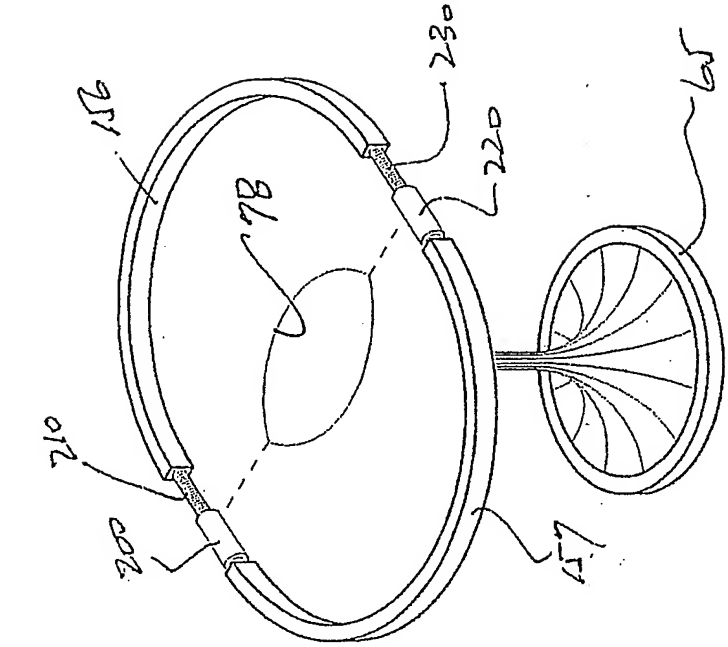

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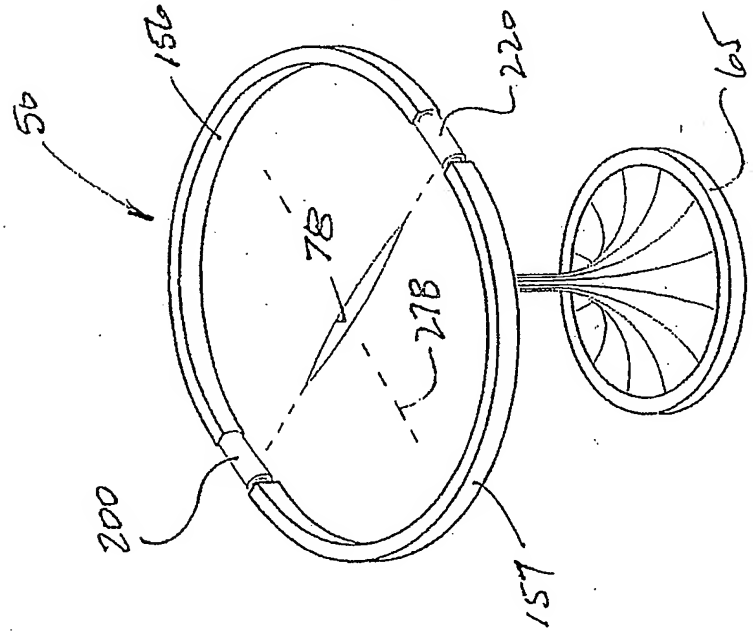

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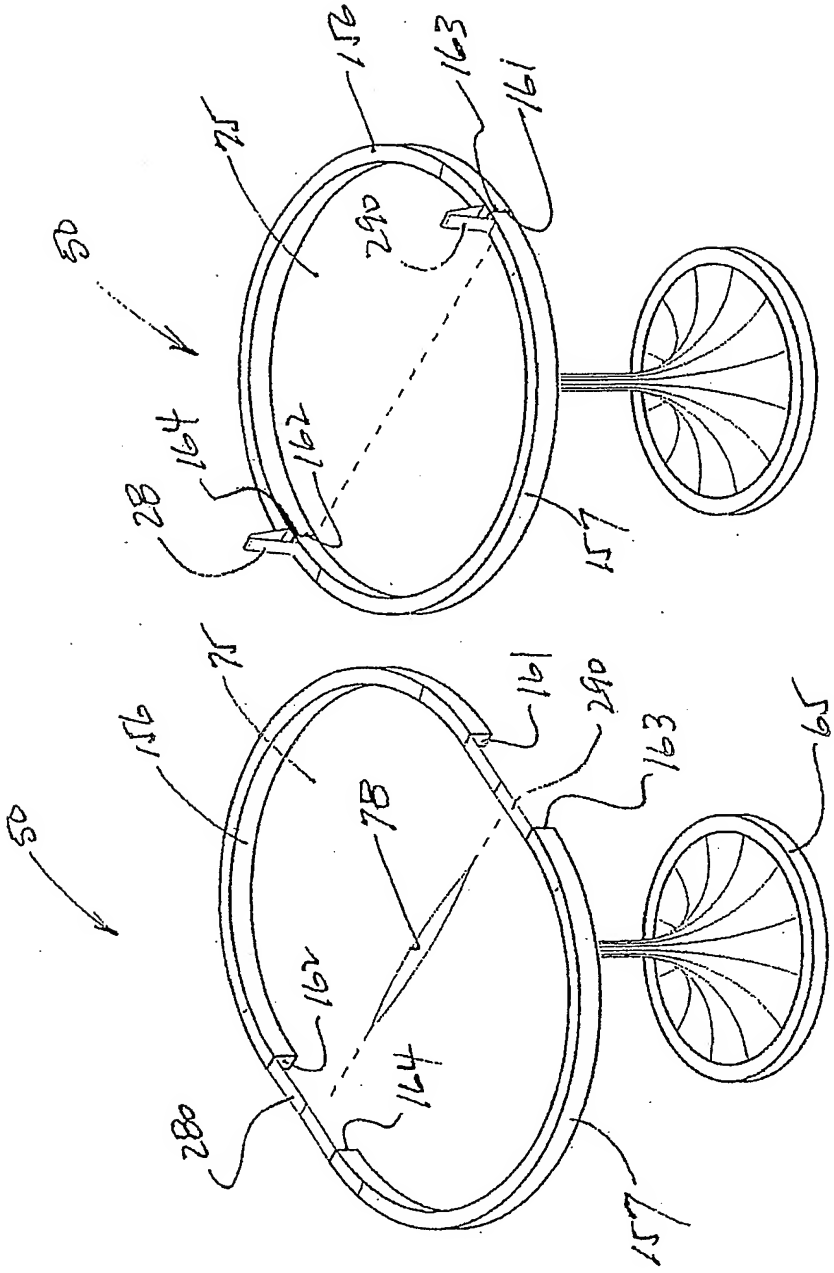
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Fig. 16

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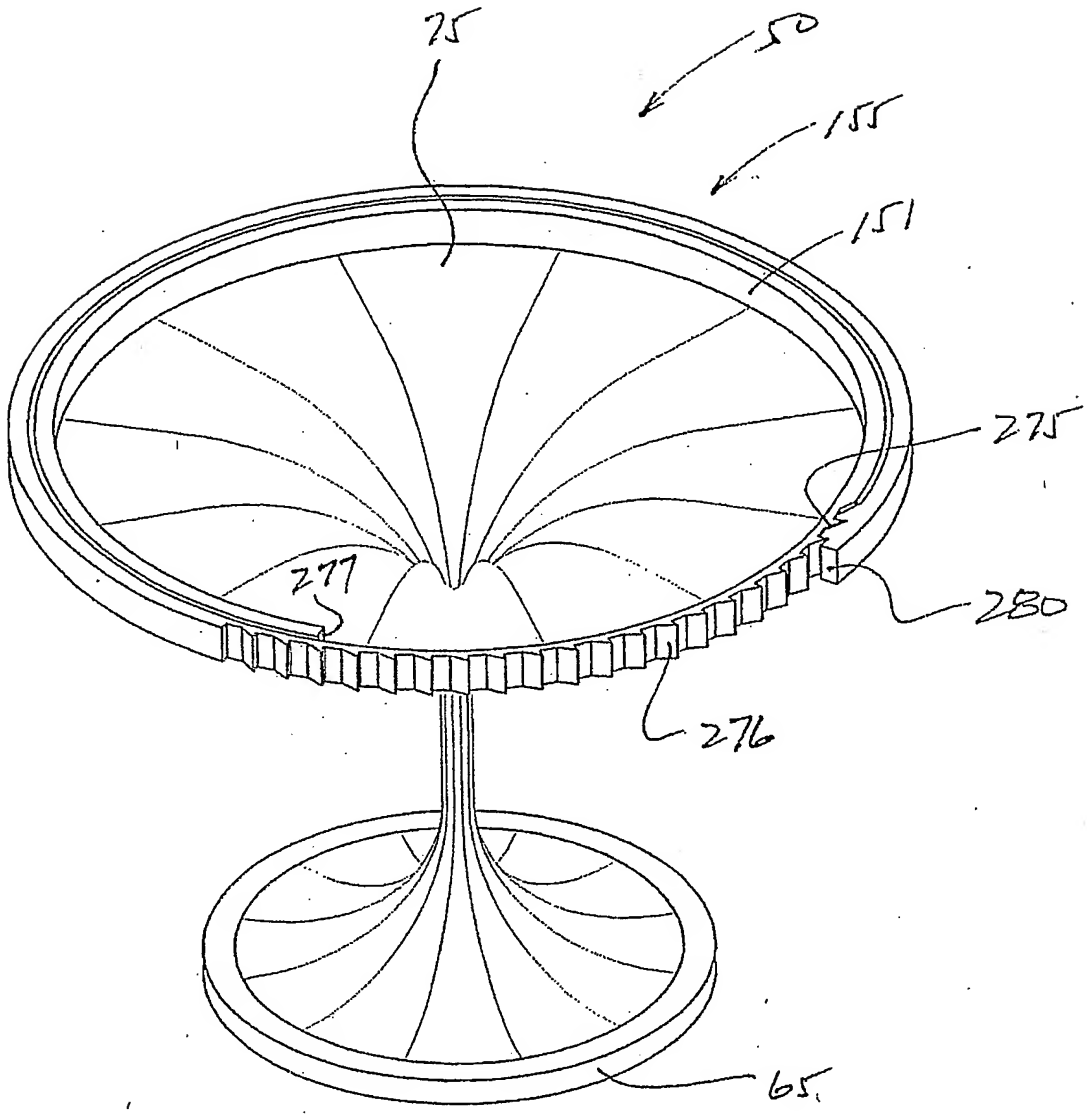
Fig. 15



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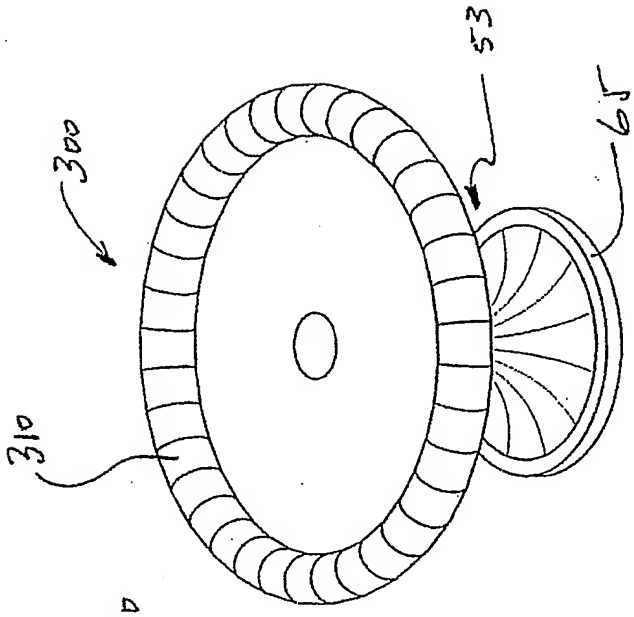
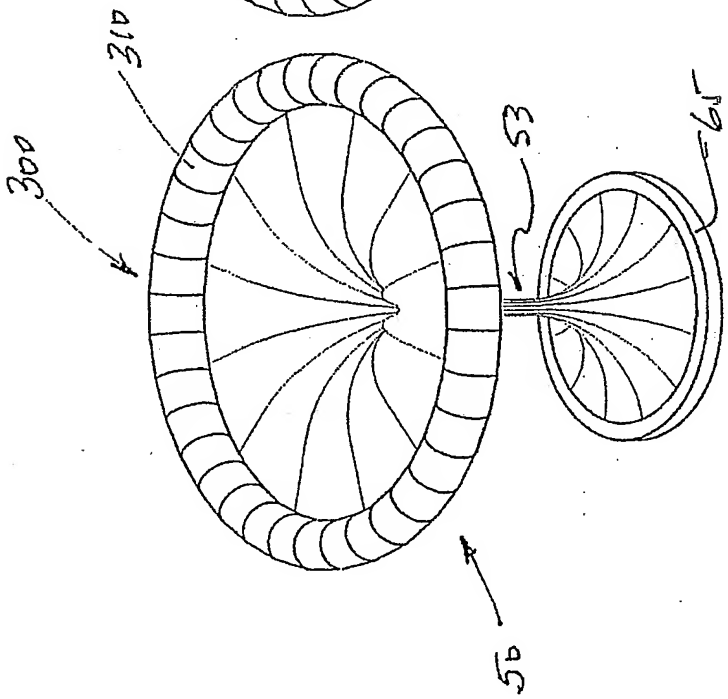


Fig. 18



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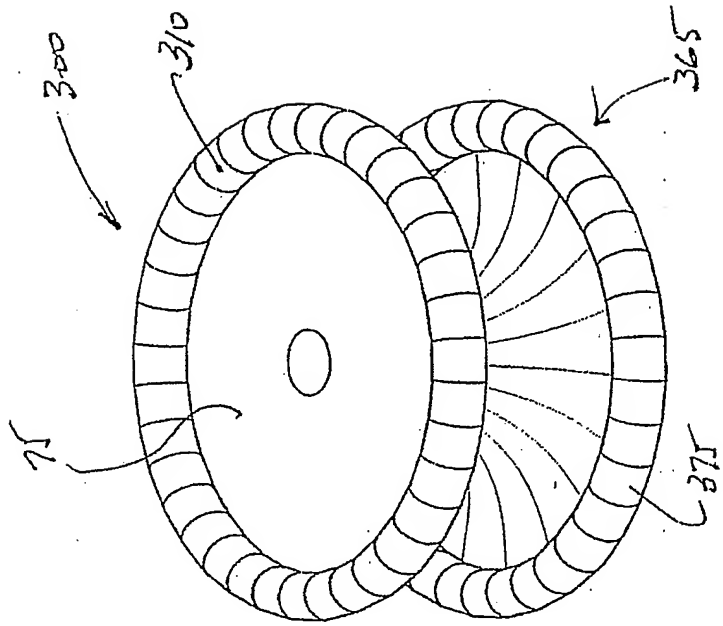

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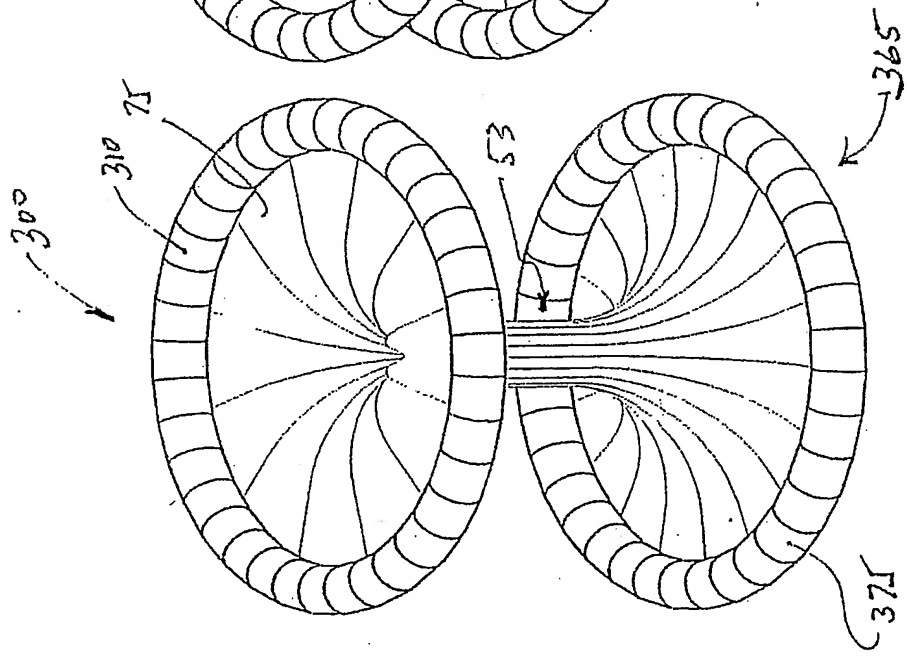
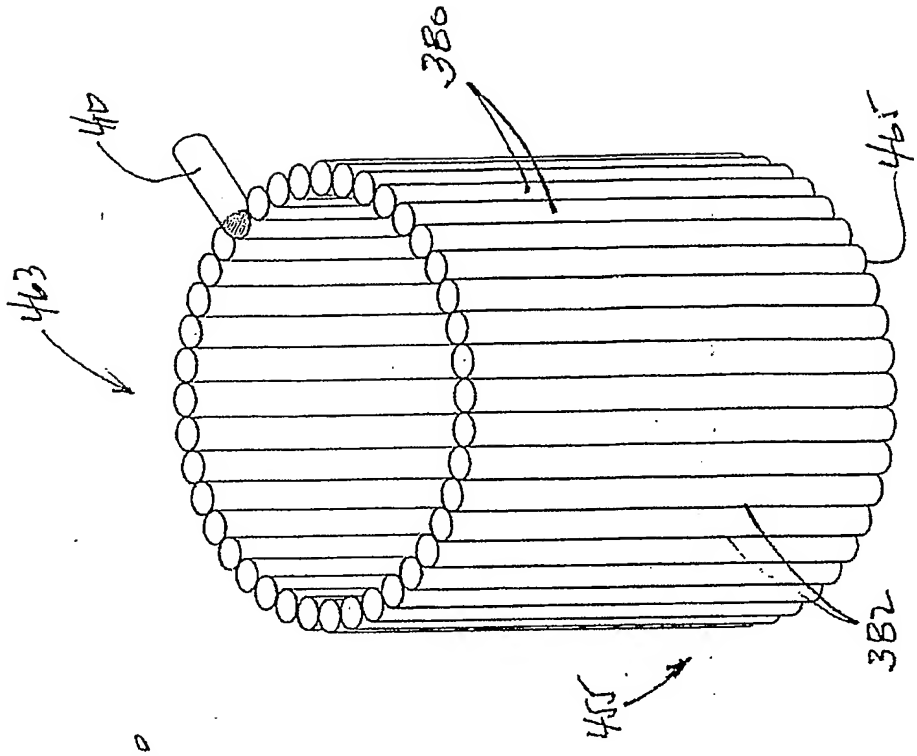


Fig. 21



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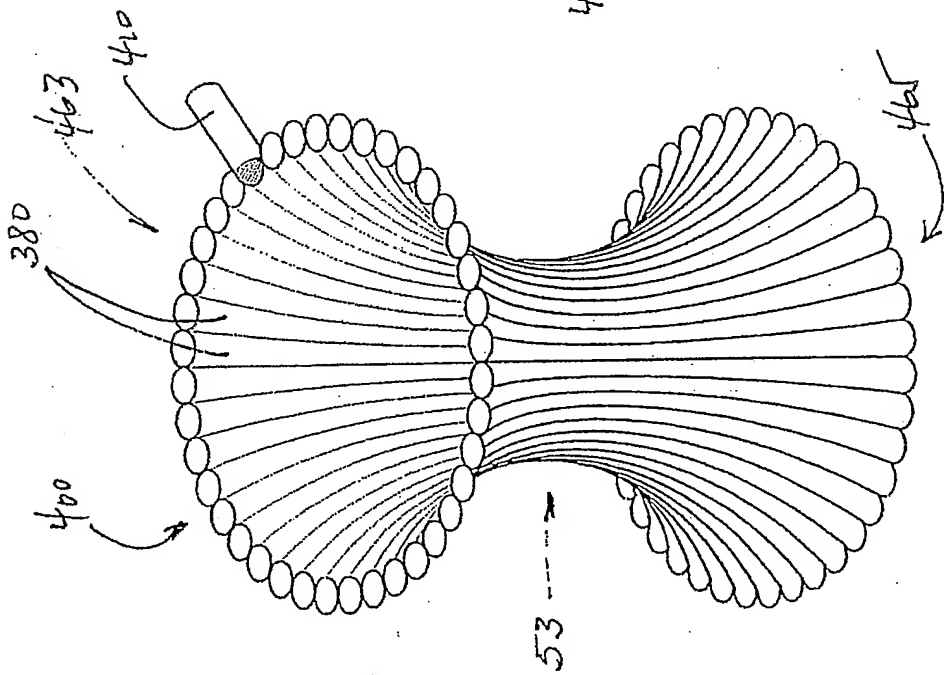

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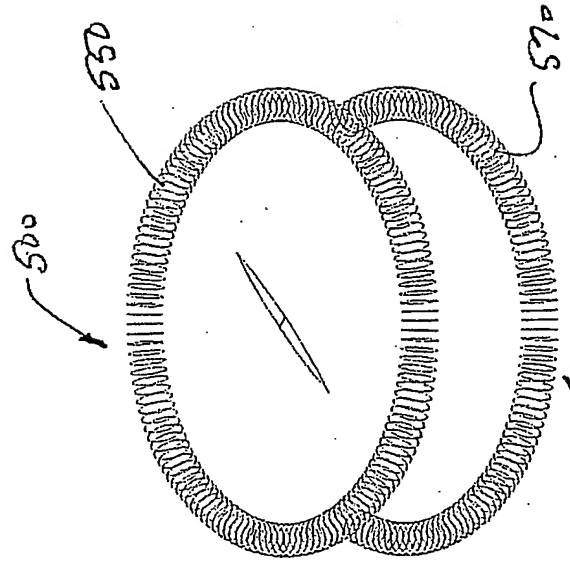

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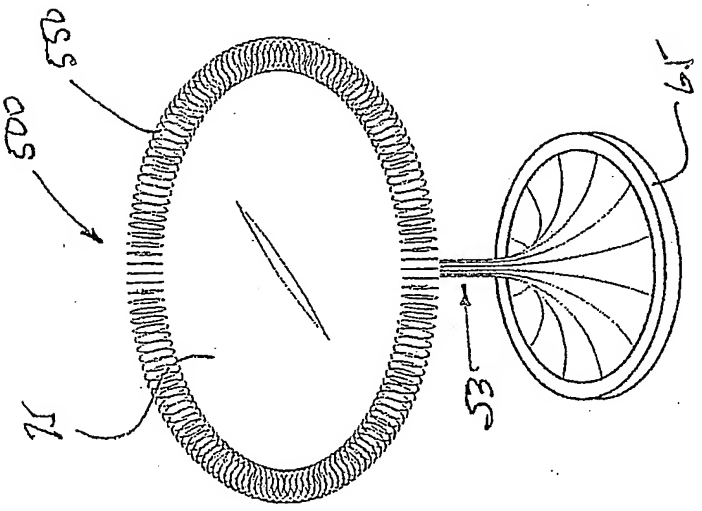

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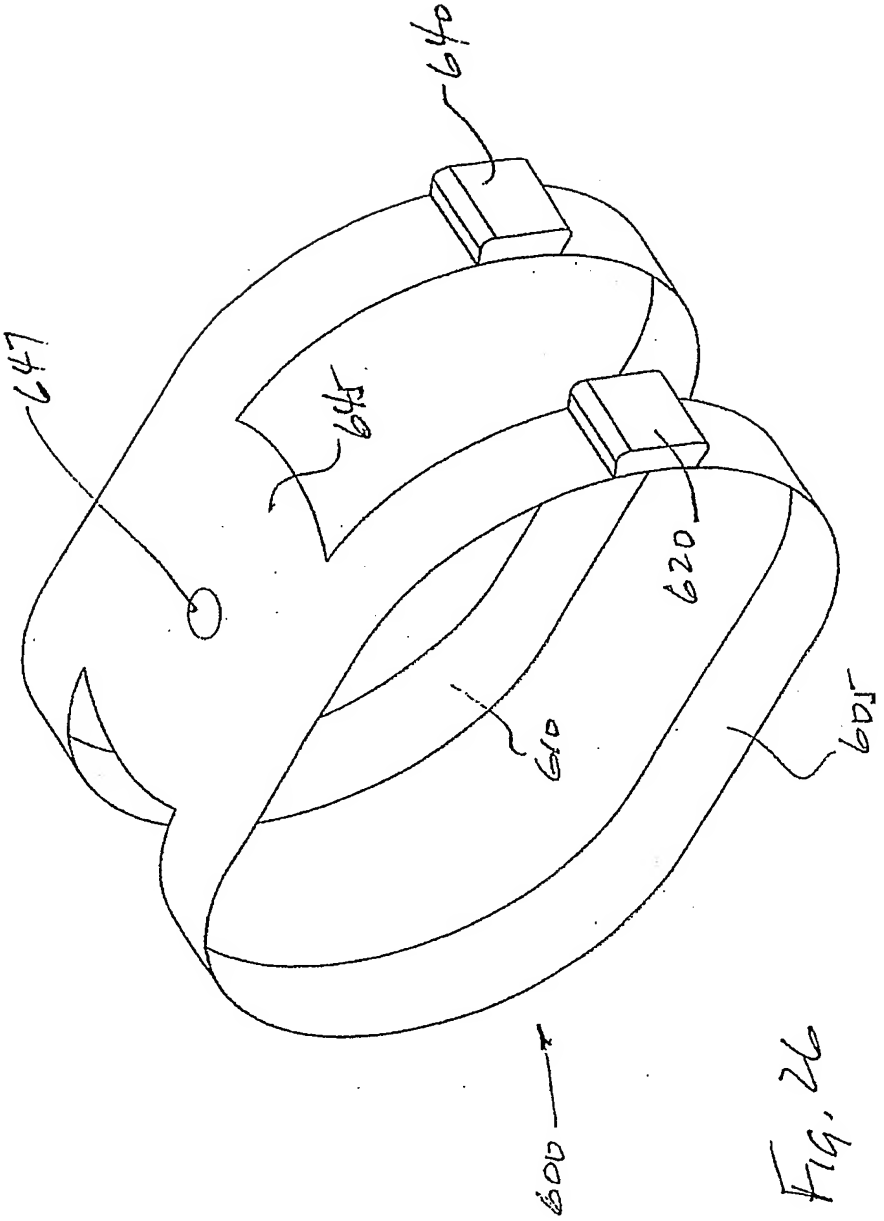

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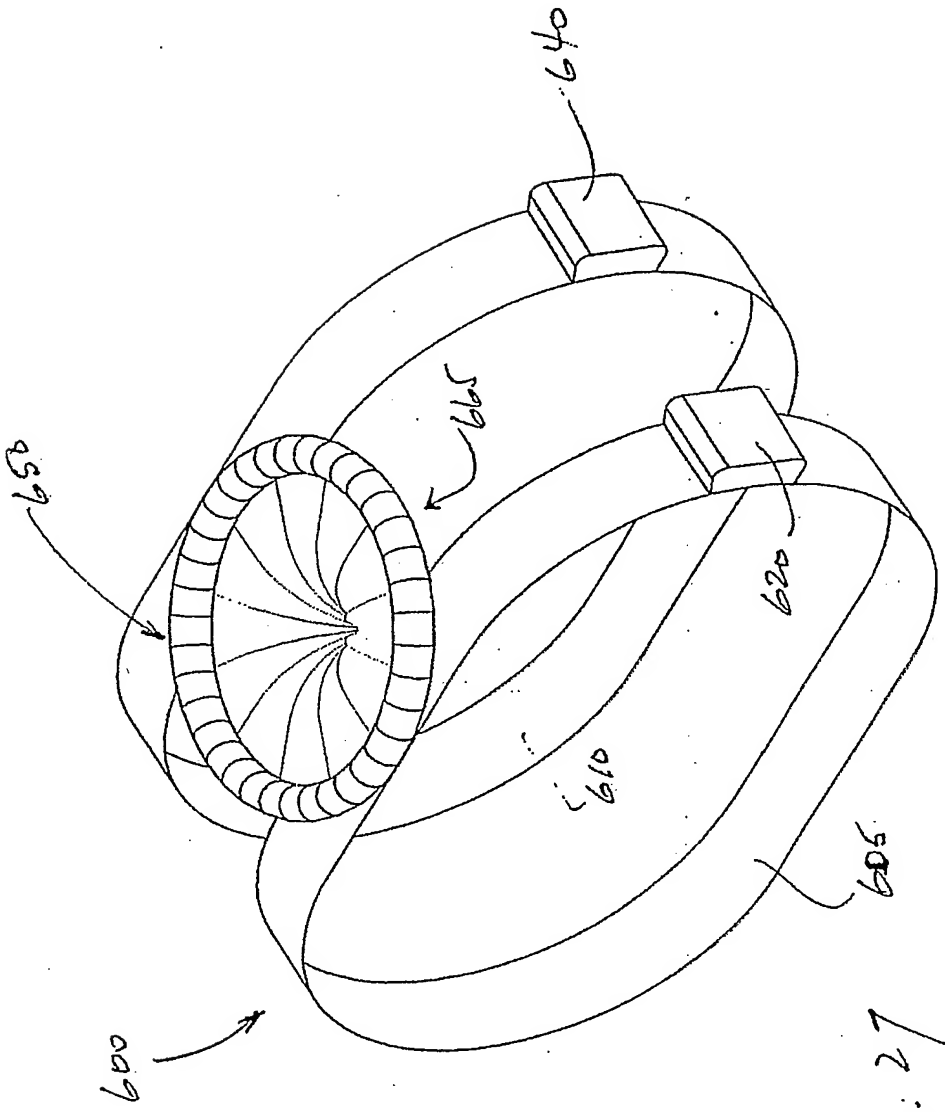
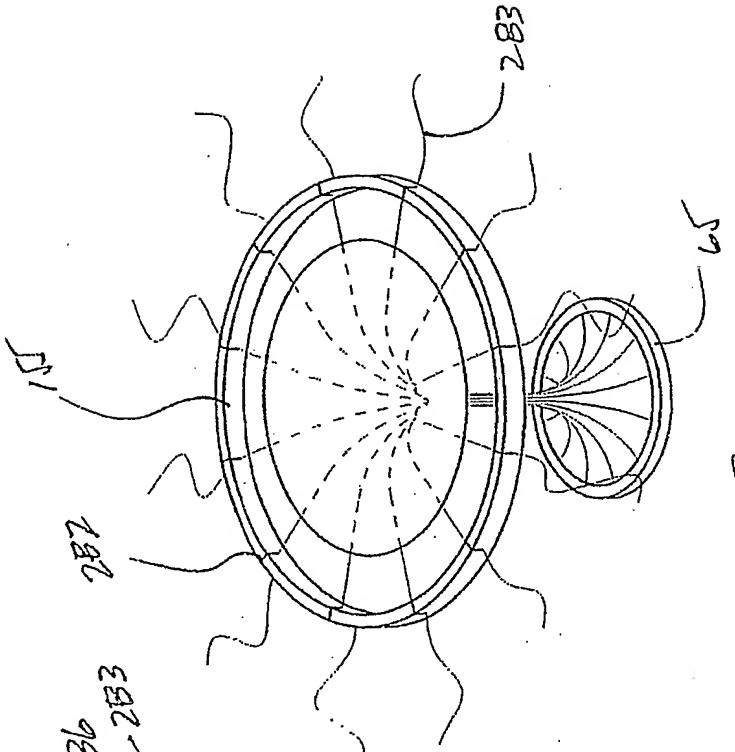


Fig. 27



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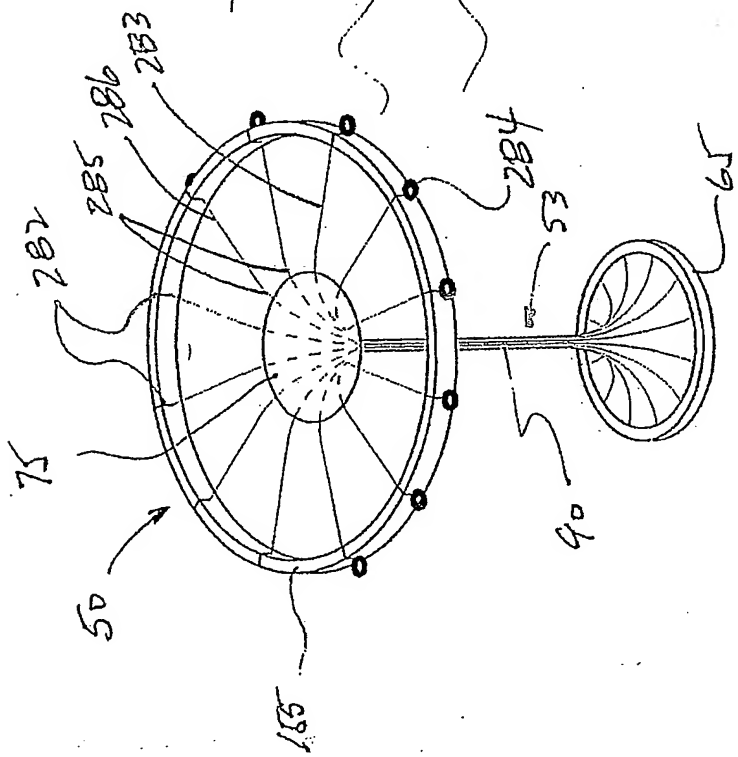

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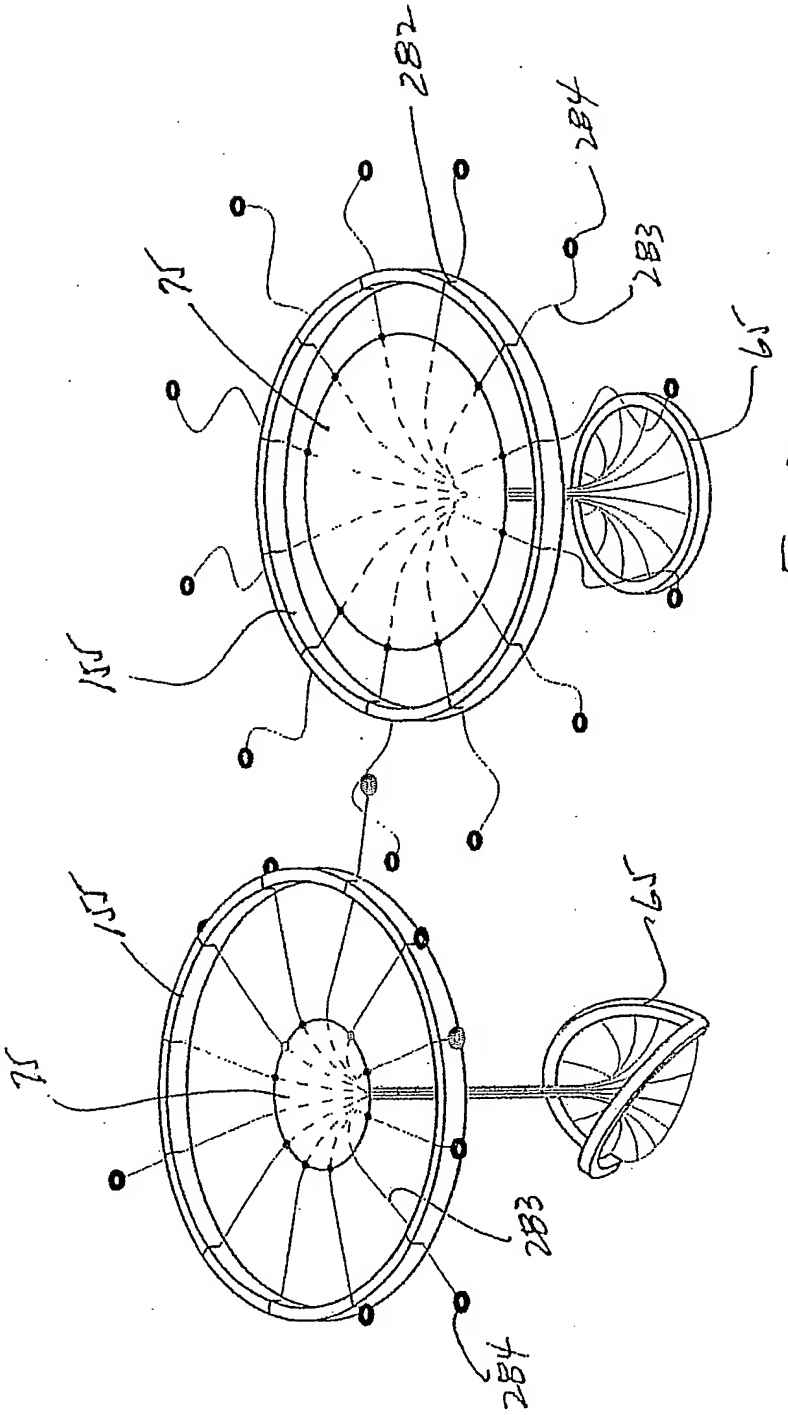
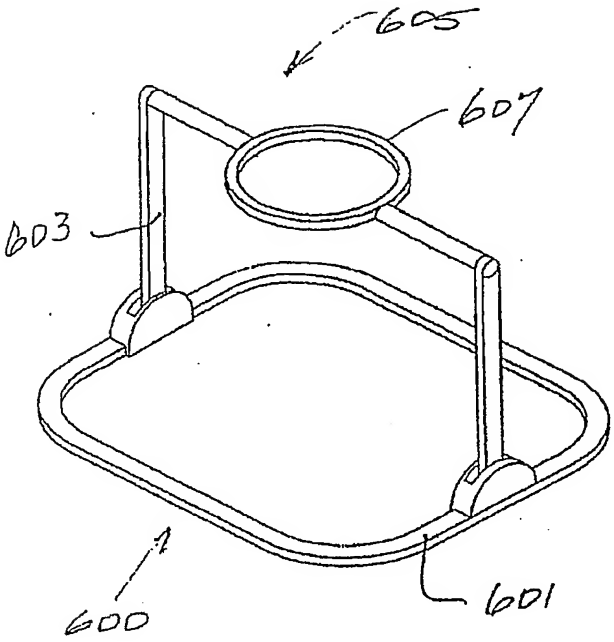


Fig. 31

Fig. 30



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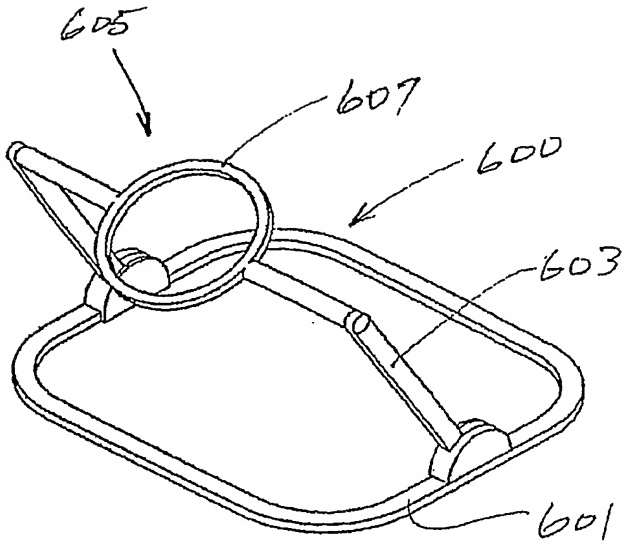

Fig. 33

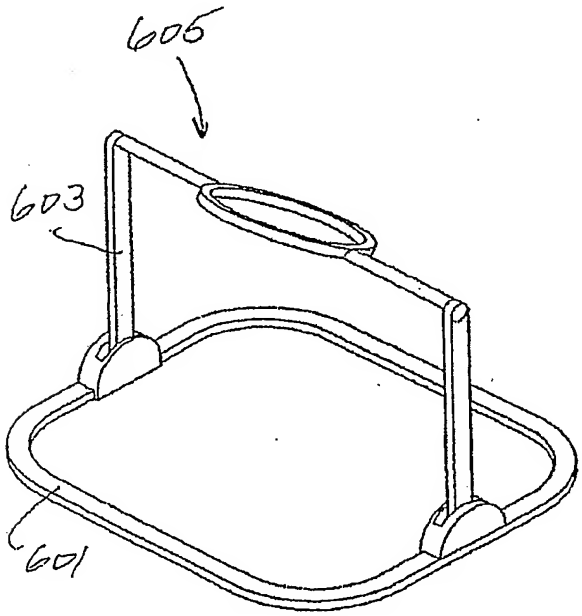

Fig. 34

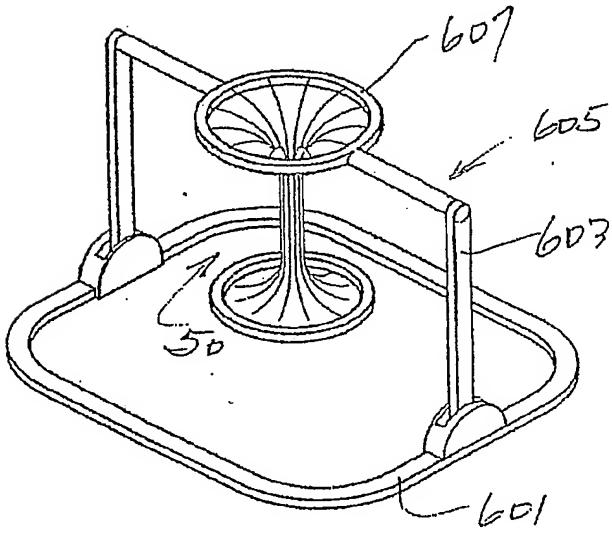

Fig. 35

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(71) Applicant *(for all designated States except US)*: **APPLIED MEDICAL RESOURCES CORPORATION** [US/US]; 22872 Avenida Empresa, Rancho Santa Margarita, CA 92688 (US).

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(74) Agent: **MYERS, Richard**; 22872 Avenida Empresa, Rancho Santa Margarita, CA 92688 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

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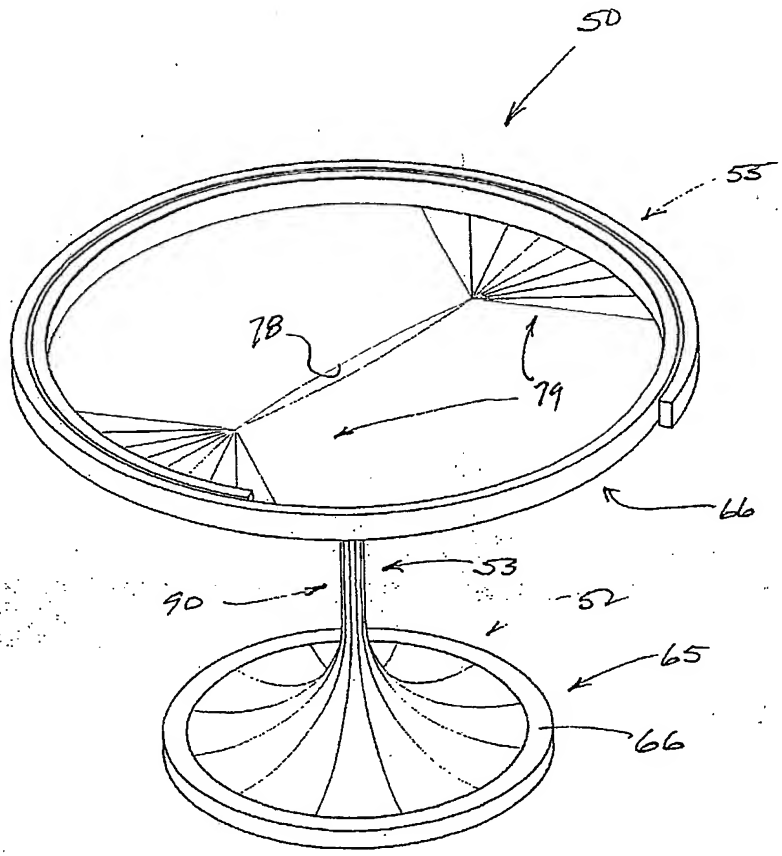
[Continued on next page]

(54) Title: SEALED SURGICAL ACCESS DEVICE



(57) Abstract: A surgical access device (50) facilitates passage of a surgeon's hand through an incision in a body wall and into a body cavity. The device includes a first retention member (55) disposed exteriorly of the body wall, a second retention member (52) disposed interiorly of the body wall, and an elastomeric sleeve (75). This sleeve has a central section (53) stretchable radially to form an instrument seal around the surgeon's hand, and stretchable axially to form a zero seal in the absence of the surgeon's hand. Stretching of the sleeve (86) is facilitated by varying the size of the first retention member (55).

WO 2004/075730 A3

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Applicant's or agent's file reference PB1-2018-AL	**IMPORTANT NOTICE**

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PCT/US2004/005484	25 February 2004 (25.02.2004)	25 February 2003 (25.02.2003)

Applicant
APPLIED MEDICAL RESOURCES CORPORATION et al

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US04/05484

A. CLASSIFICATION OF SUBJECT MATTER
IPC(7) : A61B 1/32
US CL : 600/206
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 600/184, 201, 204, 205, 206, 207, 208, 209, 235; 606/213, 215, 216

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 2002/0072762 A1 (BONADIO et al) 13 June 2002 (13.06.2002), Figures 102-113, paras [0206] and [0211].	1-4, 10-13 --- 5-9, 14-15
Y	US 4,875,482 A (HARIRI et al) 24 October 1989 (24.10.1989), Figure 6 and column 8, lines 62-63.	7, 14
Y	US 5,674,280 A (DAVIDSON et al.) 7 October 1997 (7.10.1997), Figure 1.	6
Y	US 6,391,054 B2 (CARPENTIER et al) 21 May 2002 (21.05.2002), Figure 1, column 5, lines 51-61.	8, 9, 15
Y	US 5,207,687 A (BERNON), 4 May 1993 (4.05.1993), Figure 1, column 3, lines 11-28.	5
X	US 2001/0037053 A1 (BONADIO et al) 1 November 2001 (1.11.2001), Figure 11, paras [0083]-[0085].	1-4, 10-13 --- 5-9, 14-15

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* *Special categories of cited documents:*

"A" document defining the general state of the art which is not considered to be of particular relevance

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Date of the actual completion of the international search	Date of mailing of the international search report
01 October 2004 (01.10.2004)	12 NOV 2004
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Kevin Shaver Telephone No. (703) 308-0858

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